

Kuali Research

California State University, Fresno

Committee for the Protection of Human Subjects (CPHS)

Guide for Creating, Reviewing, and Managing IRB Protocols

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Logging In

Step No.	Instructions
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|---|--|
| 1 | Navigate to: https://csufresno.kuali.co/protocols/new?protocolType=IRB |
|---|--|
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Enter your Fresno State email credentials.

- | | |
|---|--|
| 2 | Username: <enter your username> |
| | Password: <enter your password> |
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Creating a New Protocol

Step No. Instructions

- 1 From the **Manage Protocols** screen:
- Click the **+ New Protocol** button and select **IRB**.

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- The Kuali Research **Protocol** document will open. Complete the information as indicated below:
- 2
- **Principal Investigator:** **Name of the lead faculty researcher or faculty advisor**
 - **Lead Unit:** **The department or unit that will review the protocol**
 - **Title:** **Your protocol title**
 - Click the **Next** button in the upper right-hand corner of the screen.

-
- The **General Questionnaire** will open.
- 3
- Is your protocol funded? Select yes or no.
 - At the bottom of the page, indicate whether your protocol is “minimal risk” or “at risk.”


Note: If your protocol is less than minimal risk and exempt from human subjects review, you will need only a memo from your department chair or unit director confirming the exemption. You do not need to submit a protocol through Kuali.

-
- The full protocol will open. Complete the fields with data that is appropriate to your protocol and press the **Submit** button.
- 4
- Clear any errors that display through your protocol form. Any errors will be highlighted in red.
 - Press the **Submit** button again and confirm that the protocol screen goes into a Read Only mode and the status updates to **Submitted for Review**.

Searching for Protocols

Step No. Instructions

From the **Home** screen:

- 1
 - Click the **Manage Protocols** page and click the **Advanced Filter**  button at the top of the screen.
 - Select **No Filter** in the **Saved Filters** dropdown.

Click **Advanced Filter** and enter the following details.

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

In the displayed search results:

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

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- 4 Navigate through the protocol and review the information in the document.
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Departmental/Unit IRB Review

Step No. Instructions

For departmental/unit IRB chairs:

- 1 From the **Dashboard** (top of left-hand side of Kuali IRB homepage) click on **New** on the **IRB - Needs Attention** gadget.

All protocols submitted for your departmental/unit IRB review should show up in your list.

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

Click the **Review Assignments** button on the right-hand action bar and enter the following details:

- 3
 - **Review Type:** **Full Board**
 - **Committee:** Enter the name of your departmental/unit IRB committee.
 - Assign departmental reviewers by selecting names and designating a review type [e.g., "primary reviewer," "secondary reviewer"]. (Note: The reviewer types have the same functionality, but a reviewer type must be selected to assign that reviewer.)
 - If relevant, assign a review deadline.
 - Click the **Assign** button at the bottom of the page.

The departmental/unit IRB members assigned by the chair should now see the protocol in their "Protocols Assigned to Me" list on their Kuali homepage.

For all assigned departmental/unit IRB members:

- 4
 - Click on the title of the protocol assigned for your review.
 - Scroll through the protocol and review answers to the questions.
 - Download attachments for review.
 - To make comments or request revisions on protocol sections for the PI, click **Action Item**, enter your comment, and select who should have access to the comment (assigned reviews, researchers, or both).
 - Click **Post** at the bottom of the Action Item comment.

To request revisions from the PI:

Press **Require Revisions** and complete the following fields:

- 5
- **Decision Date:** Leave as current date.
 - **Date Revisions Are Due:** If applicable, assign a revision deadline for the PI.
 - **Comments:** Type any comments you want the PI to see (Example: "Please review all Action Items and make appropriate revisions to the protocol.")
 - Click the **Send** button at the bottom of the dialog.

To approve a protocol (if a protocol requires department IRB review only):

Scroll down to the bottom of the protocol page where it says **Department Risk Review**.

- 6
- In the **Risk Level of Protocol** section, confirm the risk level of the project ("minimal risk" or "at risk").
 - If applicable, write any comments in the **General Review Comment** section.
 - Check the **I approve this protocol** box.
 - Type your name in the **Department Reviewer** field to indicate your electronic signature.
 - Scroll to the top of the screen, click on **Protocol**, and press **Submit Review**.
 - Only if you are the IRB Chair: Once all approvals have been submitted, on the right-hand side of the screen select **Approve**, type any **Approval Comments**, and confirm your approval by selecting **Approve**.

If disapproving a protocol, select **Disapprove** on the right-hand side of the screen. Note that approval and disapproval actions cannot be undone after submission.

To forward a protocol for University CPHS review (if a protocol is externally funded or "at risk"):

- 7
- If a protocol is externally funded or designated as "at risk" by the department/unit IRB committee, the protocol should NOT be approved at the department level and should be forwarded to the University CPHS for final approval.
 - To indicate approval by the department IRB committee, type "This protocol has been approved by the [name of department/unit] IRB" in the **General Review Comment** section.
 - Click on **Review Assignments** in the right-hand toolbar and assign **Jennifer Randles** (CPHS Chair) as the **Admin Reviewer**.
 - Press the **Assign** button in the lower right-hand corner of the screen.
 - If you would like to confirm CPHS receipt, email Dr. Jennifer Randles at: jrandles@csufresno.edu.

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.
 - All requested revisions should display at the top of the screen under the heading **Feedback** and under the **Action Item** button for each protocol section.

- 2
 - Scroll down to the protocol section that requires revision and make necessary changes.
 - Click **Reply** to the Action Item and type in a response.
 - Press **Post** at the bottom of the reply.
 - Repeat these steps for all fields with an Action Item.

- 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.

Departmental Review of Revisions Made by the Researcher

Step No. Instructions

From the **Dashboard** click on **Resubmitted** on the **IRB - Needs Attention** gadget. Revised protocols should also display in the **Protocols Assigned to Me** list.

- 1
 - Find the relevant protocol and click on the **Title**.
 - Click on **Show Latest Changes** and scroll through the protocol to review the changes made by the researcher.
 - If additional revisions are required, type those in the relevant **Action Item** fields.

To approve a protocol after revision:

Scroll down to the bottom of the protocol page where it says **Department Risk Review**.

- 2
 - In the **Risk Level of Protocol** section, confirm the risk level of the project (“minimal risk” or “at risk”).
 - If applicable, write any comments in the **General Review Comment** section.
 - Check the **I approve this protocol** box.
 - Type your name in the **Department Reviewer** field to indicate your electronic signature.
 - On the right-hand side of the screen select **Approve**, type any **Approval Comments**, and confirm your approval by selecting **Approve**.
 - Scroll to the top of the screen, click on **Protocol**, and press **Submit Review**.

If disapproving a protocol, select **Disapprove** on the right-hand side of the screen. Note that approval and disapproval actions cannot be undone after submission.

To forward a funded or “at risk” protocol for University CPHS review:

- 3
 - If the approved protocol is funded or designated as “at risk” by the departmental committee, the protocol should be forwarded to the University CPHS.
 - Click on **Review Assignments** in the right-hand toolbar and assign **Jennifer Randles** (CPHS Chair) as the **Admin Reviewer**.
 - Press the **Assign** button in the lower right-hand corner of the screen.
 - If you would like to confirm CPHS receipt, email Dr. Jennifer Randles at: jrandles@csufresno.edu.

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 screen.
 - Enter a justification for your amendment.
 - To add study personnel, scroll down and select **+Add Item** on the person list and complete the person, department, and researcher role fields. Scroll down to the bottom of the dialog and press **Done**.
 - To edit sections of the protocol, scroll down to the **Protocol** section and change your answers in the relevant fields.
 - 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.
 - Review all sections of your previously submitted protocol to ensure no amendments are necessary.
 - Press the **Submit** button.

To close your study protocol:

- 4
 - Click the **Request Close** button in the upper right-hand corner of the screen.
 - Answer questions about initiation of study activities.
 - Press the **Submit** button.