Review a Protocol and Write Comments or Recommend for Approval

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If you have questions, please:
- Check the eProtocol IACUC Reviewer Quick Guides on the ACUC website.
- Contact the OACU at 642-8855 or acuc@berkeley.edu

A. The Protocol Review Process

1. Once a protocol is submitted to ACUC for review, the OACU conducts a preliminary review to assure a protocol is acceptable for review.
   a. The OACU may return a protocol to the PI with suggested changes.
   b. The PI, Laboratory Contact & Administrative Lab Contact all receive an email when a protocol is returned by the OACU.
   c. The PI and Laboratory Contact or Administrative Lab Contact can review and respond to the comments, edit the protocol, and re-submit the protocol back to the ACUC/OACU for further review.

2. Once the OACU accepts the protocol for review, the method of review is determined based on the criteria outlined in the ACUC Policy and Procedures on Protocol Review:
   a. Designated Member Review (DMR)
   b. Full Committee Review (FCR)
   c. Administrative Review

3. All reviewers receive email notification from eProtocol when they are assigned as a Reviewer, which directs them to log into eProtocol, https://eprotocol.berkeley.edu.
   a. The email notification will indicate:
      i. The Meeting Date
      ii. Protocol Number
      iii. PI Last Name
      iv. PI Department
      v. The Review Type (DMR or FCR)
   b. Refer to the Reviewer Homepage Quick Guide for additional information about logging into eProtocol, how to view/read protocols, and how to start/continue to the review process.
4. Reviewers Functions include:

   a. **Submit a review decision**, indicating whether a protocol should go DMR or FCR (DMR call to FCR).

   b. **Recommend approval** for a DMR or FCR protocol.
      i. Only the Presenter, Primary & Secondary Reviewers can recommend for approval.
      ii. FCR protocols are discussed and voted on at a convened ACUC meeting.

   c. **Submit questions or comments** to the OACU, to forward onto the PI.

5. The OACU collects all Reviewer comments/questions, compiles them and “sends” them to the PI via eProtocol.

   a. The comments are incorporated into a “Comments” section associated with the protocol form. The PI responds to the comments and make any necessary changes to the protocol.

   b. The PI, Laboratory Contact & Alternate Lab Contact all receive an email when comments are “sent” by the ACUC/OACU.

   c. The PI, Laboratory Contact or Administrative Lab Contact can review/respond to the comments, edit the protocol, and submit the responses/changes back to the OACU for further review.

6. This process continues until all comments are resolved and all the Reviewers can recommend the protocol for approval.

   a. FCR protocols are discussed and voted on at a convened ACUC meeting. Recommending an FCR protocol for approval does not take the place of the committee discussion and vote at the meeting. It only indicates that the assigned reviewers have no further comments.

**B. DMR Call to FCR**

1. All reviewers receive an email when a protocol is under consideration for DMR.

   a. Reviewers will have **one working day** to respond with a call to FCR.

2. Log in to eProtocol with your CalNet ID & password at: [https://eprotocol.berkeley.edu](https://eprotocol.berkeley.edu)

3. UC Berkeley uses both IACUC and IRB modules of eProtocol. Click on the **IACUC** tab to see your ACUC Reviewer Home Page.

4. If you have an Investigator role in eProtocol, the system opens to the Investigator Home page by default.
a. Using the menu in the top left margin, click on **Reviewer** or **Reviewer Home**. (see screen shot, next page)

5. The DMR call to FCR protocol will be highlighted in pink on the Reviewer Home Page.

6. Click on the **Protocol ID** to view the protocol.

7. Click on the **Protocol Event** link to continue the review process.
   a. The **Review Decision** pop-up window will open.
   b. Click **Get Protocol** to view the protocol
   c. Click on **Review Decision** to submit a review decision.
8. Select either **Designated Review** (DMR) or **Full Review** (FCR) and **Submit**.

   - You can submit **Notes to the IACUC** (OACU) along with your decision.
   - If no full committee reviews are submitted by reviewers (Call to FCR) **within 3 working days**, DMR review of the protocol will proceed.

**C. DMR/FCR Review**

1. All reviewers receive an email when they are assigned to a DMR or FCR protocol.
2. Log in to eProtocol with your CalNet ID & password at: [https://eprotocol.berkeley.edu](https://eprotocol.berkeley.edu)
3. Click on the **IACUC** tab to see your ACUC Reviewer Home Page.
4. If you have an Investigator role in eProtocol, the system opens to the Investigator Home Page by default.
   - Using the menu in the top left margin, click on **Reviewer** or **Reviewer Home**.
5. On the **Reviewer Home Page**, you can only view protocols that you have been assigned to review.
   - See the [eProtocol User Guide on Understanding Your Reviewer Home Page](https://eprotocol.berkeley.edu) for more information.
6. Click on the **Protocol ID** link to view the Protocol

7. Click on the **Protocol Event** link to continue the review process. This opens the Comments page associated with the protocol.

   a. The **Review Type** (DMR, FCR) is at the top of the page.

   b. To read the protocol, click **Get Protocol**.

   c. Reviewers can:

   i. **Recommend for Approval**
      - Presenter, Primary & Secondary Reviewers only

   ii. **Write Comment(s)**

If you have no questions or comments for the PI, click **Recommend for Approval**

If you have questions or comments for the PI, click **Write Comments**.
d. To Recommend for Approval:

i. Click on Recommend for Approval, which opens the Approval Notes window.
ii. Click the radial “protocol is satisfactory” button.
iii. You can write notes to the IACUC (OACU). The PI will not see these notes.
iv. Click on Submit to the IACUC (OACU).

v. For DMR protocols, the protocol is not approved until all Reviewers Recommend for Approval.

vi. For FCR protocols, the protocol is presented and voted on at a convened ACUC meeting.

e. To Submit Comments to the PI:

i. From the drop-down menu, select the section of the protocol the comment refers to.
   • Each procedure in the protocol will be listed separately by title.

ii. Write your comment.

iii. Select Response Necessary or Not Necessary for Approval.
iv. Click **Save** if you are done with your comments, or **Save & Add Comment** to write additional comments.

v. When you save your comments, the **Submit to IACUC** button appears.
   - Submit your comments **only when you are done**.

vi. Once you save your comments, you can also **Edit All Comments** and the review **Cycle number** appears.

vii. After you click on **Submit to IACUC**, a **Notes to Manager** (OACU) pop-up window is displayed.

viii. Add any **Notes to Manager**. The PI will not see these notes.

ix. Click on **Submit to IACUC**.

x. After you submit your comments to the IACUC or recommend for approval, the **Protocol Event** on your Reviewer Home Page updates to **Comments sent (Cycle #)**.

The **Protocol Event** on your Reviewer Home Page updates.
xi. When you receive responses back from the PI (forwarded by OACU), you will:
   - Receive an email from eProtocol.
   - The Protocol Event indicated Responses Received (Cycle #).

xii. Click on the Protocol Event link to continue the review process.

![Protocol Event link](image)

Click on Responses Received (Cycle #) to continue your review.

xiii. Reviewers can:
   - View all the comments and responses
     - Click on Show All Comments.
   - Get the Protocol to view changes made by the PI.
     - See Reviewing Changes, below.
   - Submit further comments by clicking on Write Comment(s).
   - Recommend for Approval.

![Review page](image)

xiv. The DMR review cycle continues until either all reviewers can recommend for approval, or (if unanimous approval is not reached) the protocol is called to FCR.
xv. The FCR review cycle continues until the protocol is presented and voted on at a convened ACUC meeting.

xvi. When viewing the comments page, make sure the cycle that you are viewing, indicated in red, is the most current review cycle, or the Recommend for Approval and Submit to IACUC button will not appear.

xvii. If you have no further comments but there are outstanding questions from other reviewers that still need to be addressed by the PI, you can write a comment to this effect, and select the Suggestion Not Necessary for Approval.

- If you only have one comment, and you have selected Suggestion not Necessary for Approval, the Submit to IACUC button does not appear, only the Recommend Approval Button appears. Select the Recommend for Approval Button.
- Adding your comment in this way makes it easier for the OACU Analyst coordinating the review to view it along with the other reviewer comments.

D. Reviewing Changes Made to the Protocol

1. When you click on the Protocol Event and open the comments page, a stacked pages icon will appear next to the Protocol ID if the PI has made changes to the protocol during the review cycle.

2. To view changes the PI has made to the protocol during the review cycle, click on the Protocol ID or Get Protocol to open the protocol in view mode.

3. At the top of the left blue navigation bar, Click on Amendment or Continuing Review (dependent on the type of form that you are reviewing).
4. Scroll to the bottom of the page, where you will see Updates. Click on the Updates link that you wish to review. A drop down menu, displaying sections of the protocol that were edited by the PI will appear.

![Updates dropdown menu]

5. Click on the section of the protocol you wish to review and track-changes will appear, allowing you to view current and previous responses.

![Track-changes highlighted]

6. When viewing the AUP form, the stacked pages icon will appear if the PI made edits to this section of the form.
7. When you click on the pages icon, a Version History pop-up window appears, which shows the edits the PI made, highlighted with a track-changes tool, for each review cycle.

![Version History Table]

8. A **NEW!** balloon icon will appear in sections that the PI has added new information.

![Added Information Example]