

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

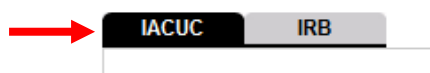
A. The Protocol Review Process

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.

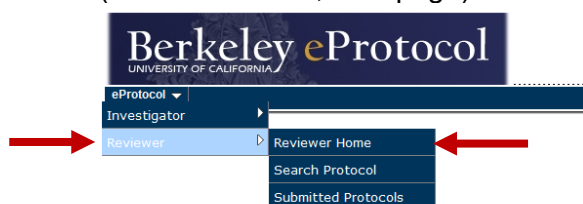
B. DMR Call to FCR

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

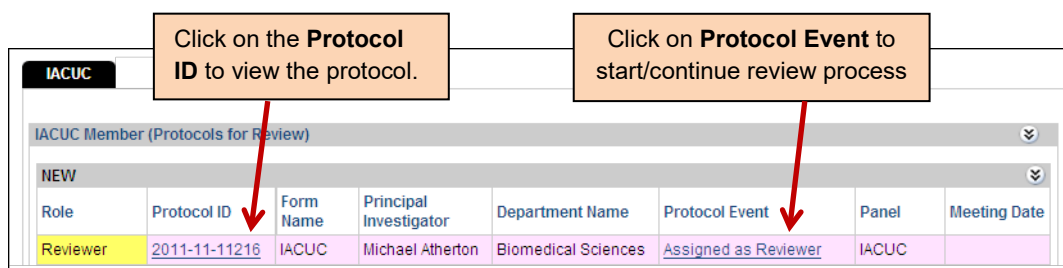


4. If you have an Investigator role in eProtocol, the system opens to the Investigator Home page by default.

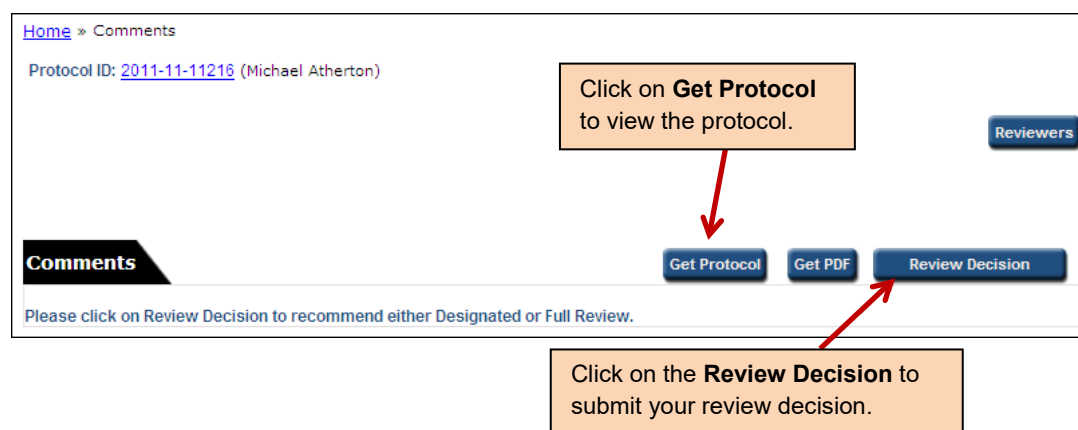
- a. Using the menu in the top left margin, click on **Reviewer** or **Reviewer Home**. (see screen shot, next page)



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.



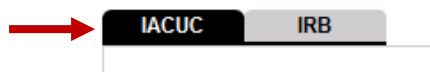
8. Select either **Designated Review** (DMR) or **Full Review** (FCR) and **Submit**.

- Select either **Designated Review** or **Full Review**
- Add any **Notes to IACUC** (OACU)
- Click **Submit**

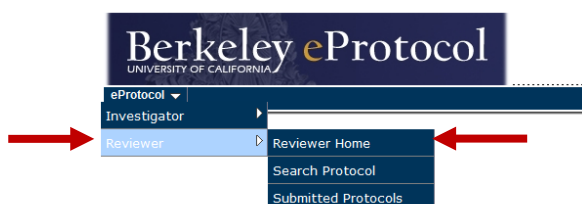
- You can submit **Notes to the IACUC** (OACU) along with your decision.
- If no full committee reviews are submitted by reviewers (Call to FCR) **within 3 working days**, DMR review of the protocol will proceed.

C. DMR/FCR Review

- All reviewers receive an email when they are assigned to a DMR or FCR protocol.
- Log in to eProtocol with your CalNet ID & password at: <https://eprotocol.berkeley.edu>
- Click on the **IACUC** tab to see your ACUC Reviewer Home Page.



- 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**.



- 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](#) for more information.

IACUC

IACUC Member (Protocols for Review)

NEW

Role	Protocol ID	Principal Investigator	Title	Protocol Event	Panel	Meeting Date
Reviewer	14-08-3780	Rachel Cameron	Troubleshooting Prof. Hayes - character limits in Study O...	Assigned as Reviewer	ACUC	10/08/2014
NPR	14-04-3724	Richelle Scales	richelle scales music study	Assigned as Reviewer	ACUC	05/14/2014
Presenter	2010-02-711	EMP-FACULTY TEST	This is Testuser protocol	Comments Sent (Cycle 1)	ACUC	11/07/2013

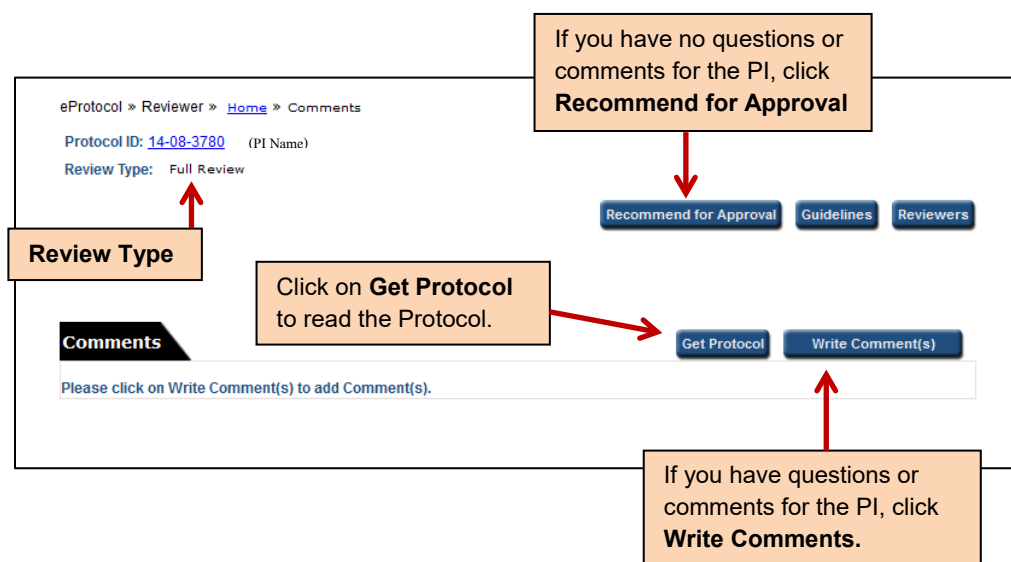
AMENDMENT

Currently there are no Amendment protocols.

CONTINUING REVIEW

Currently there are no Continuing Review protocols.

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)**



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).

- Click **“protocol is satisfactory”** button
- Add any **Notes to the IACUC** (OACU)
- Click **Submit to IACUC**

- 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.

- Select protocol section
- Write your comment
- Select **Response Necessary** or **Not Necessary for Approval**
- Click **Save** or **Save & Add Comment**.

- 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.

Review Type: Full Review

Cycle: [icon]

Comments Cycle and Edit all Comments appear after you save.

Submit to IACUC (OACU) when you are done with all your comments.

Get Protocol Write Comment(s) Show All Comments Submit to IACUC

Title: JLEE1 Select Section: Personnel Information Edit Delete

Write your questions or comments here

☐ Response Necessary for Approval
☒ Suggestion Not Necessary for Approval

- 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**.

Notes to Manager

Submit to IACUC Cancel

- Add any **Notes to Manager (OACU)**
- **Submit to IACUC (OACU)** when you are done with all your comments.

- 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 #)**.

IACUC

IACUC Member (Protocols for Review)

NEW

Role	Protocol ID	Principal Investigator	Title	Protocol Event	Panel	Meeting
Reviewer	14-08-3780	Rachel Cameron	Troubleshooting Prof. Hayes - character limits in Study O...	Assigned as Reviewer	ACUC	10/08/20
NPR	14-04-3724	Richelle Scales	richelle scales music study	Assigned as Reviewer	ACUC	05/14/2014
Presenter	2010-02-711	EMP-FACULTY TEST	This is Testuser protocol	Comments Sent (Cycle 1)	ACUC	11/07/2013

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.

Role	Protocol ID	Form Name	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Presenter	2011-11-11216	IACUC	Michael Atherton	Biomedical Sciences	Responses Received (Cycle 1)	IACUC	12/04/2011

- 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**.

Home » Comments

Protocol ID: [11-01-1306](#) (Goodwin, Scott)

Review Type: Designated Review

Cycle: [1](#)

[Recommend for Approval](#) [Guidelines](#) [Reviewers](#)

Comments

[Get Protocol](#) [Get PDF](#) [Write Comment\(s\)](#) [Show All Comments](#)

Title: BONITAK1 Reviewer: Krall, Bonita

Select Section: [Funding](#)

Test Comment

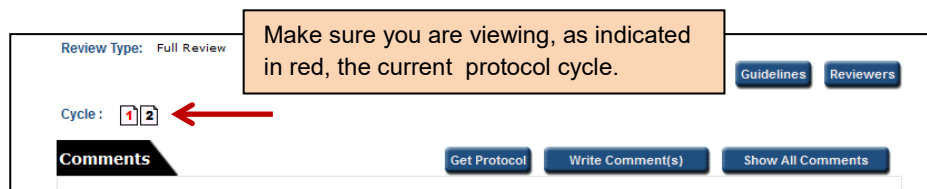
☒ Response Necessary for Approval
☐ Suggestion Not Necessary for Approval

Response

Test Response

- 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.

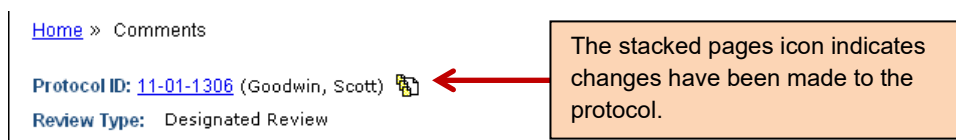
- xv. The FCR review cycle continues until the protocol is presented and voted on at a convened ACUC meeting.
- xvi. When viewing the comments page, make sure the cycle that you are viewing, indicated in red, is **the most current review cycle**, or the **Recommend for Approval** and **Submit to IACUC** button will not appear.



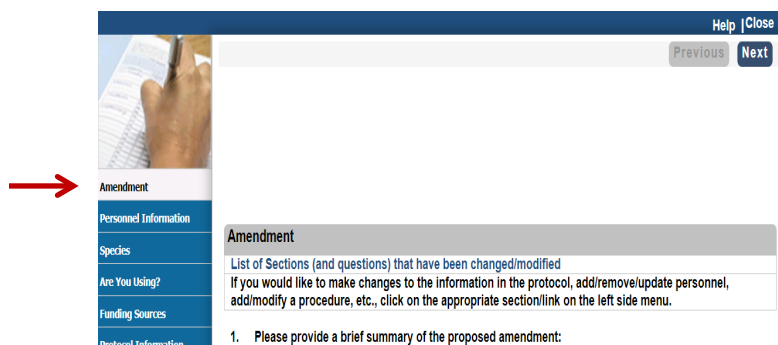
- xvii. If you have no further comments but there are outstanding questions from other reviewers that still need to be addressed by the PI, you can write a comment to this effect, and select the **Suggestion Not Necessary for Approval**.
 - If you only have one comment, and you have selected **Suggestion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



Continuing review

Personnel Information

Species

Are You Using?

Funding Sources

Protocol Information

Renewal Form

To renew this protocol, answer the following renewal questions. If you would like to make changes to the information in the protocol, add/remove/update personnel, add/modify a procedure, etc., click on the appropriate section on the left side menu.

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.

Expand Collapse

Updates - Cycle Cycle 2 (Current)

No Updates available for current version

Updates (Cycle 1)

Are You Using?

Updates (AMENDMENT)

Select the section of the protocol you wish to review

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.

Updates (Cycle 1)

Are You Using?

Controlled Substance(s) *

Current Response

☐ Yes ☐ No

Previous Response

☐ Yes ☒ No

Controlled Substance »

Caption	Current response	Previous response
Species	Mouse Laboratory	
Agent	Ketamine	
Agent (Other)		
Are all personnel who will be working with these agents registered with EH&S?	Y	
Storage Location	UC Berkeley campus	
Storage Location(Other)		

Track-changes appear as highlighted text. Current text is green. Previous text is red.

6. When viewing the AUP form, the stacked pages icon will appear if the PI made edits to this section of the form.


4. Non-pharmaceutical Grade Compounds *

NOTE: Federal regulations require the use of pharmaceutical grade compounds in animals used for research and teaching unless those compounds are not available or are otherwise inappropriate for the aims of the proposed animal use. Please refer to the [ACUC Policy](#) on Use of Non-Pharmaceutical Grade Compounds

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		
Cycle 2		
Caption	Current Response	Previous Response
Non-pharmaceutical Grade Compounds *	<u>NY</u> ←	N
Cycle 1		
Caption	Cycle 1 Response	Original Submitted Response
Non-pharmaceutical Grade Compounds *	N	N

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

4. Non-pharmaceutical Grade Compounds * 

☒ Yes ☐ No

NOTE: Federal regulations require the use of pharmaceutical grade compounds in animals used for research and teaching unless those compounds are not available or are otherwise inappropriate for the aims of the proposed animal use. Please refer to the [ACUC Policy](#) on Use of Non-Pharmaceutical Grade Compounds

Non-pharmaceutical Grade Compounds		
Species	Specify Material(s)	Please provide justification for use of non-pharmaceutical compounds
<input type="checkbox"/> <u>Mouse Laboratory (OLAC vivarium)</u> 	Nanoviricides experimental anti-viral compounds	These compounds are only available in non-pharmace....