

## Review Protocol and Write Comments or Recommend for Approval

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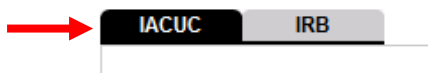
### A. The Protocol Review Process

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 & Alternate Lab Contact all receive an email when a protocol is returned by the OACU.
  - c. The PI, Laboratory Contact or Alternate 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** whether a protocol should go DMR or FCR (DMR call to FCR).
  - b. **Recommend approval** for a DMR or FCR protocol.

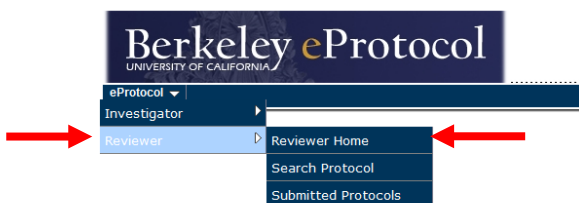
- i. Only Presenter, Primary & Secondary Reviewers can recommend for approval.
    - ii. FCR protocols are discussed and voted on at a convened ACUC meeting.
  - c. **Submit questions or comments** for the PI to OACU via eProtocol.
5. The OACU collects all Reviewer comments/questions, compiles them and “sends” them to the PI via eProtocol.
- a. The comments are incorporated into a new “Comments” section of the protocol form. The PI opens the protocol to respond 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 Alternate 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.

**B. DMR Call to FCR**

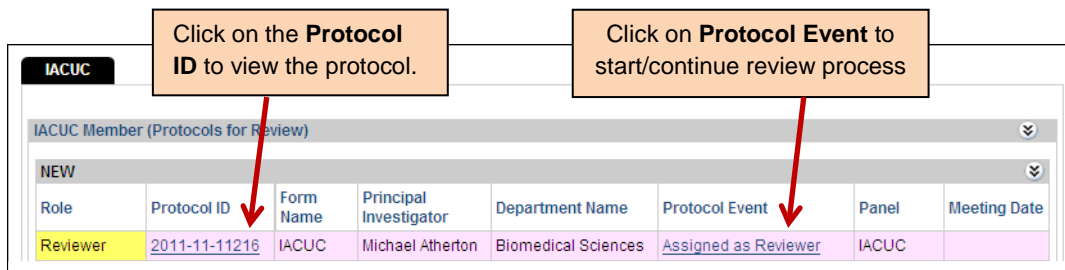
1. All reviewers receive an email when a protocol is under consideration for DMR.
  - a. Reviewers will have **3 working days** to respond with a call to FCR.
2. Log in to eProtocol with your CalNet ID & password at: <https://eprotocol.berkeley.edu>
3. UC Berkeley uses both IACUC and IRB modules of eProtocol. 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**.



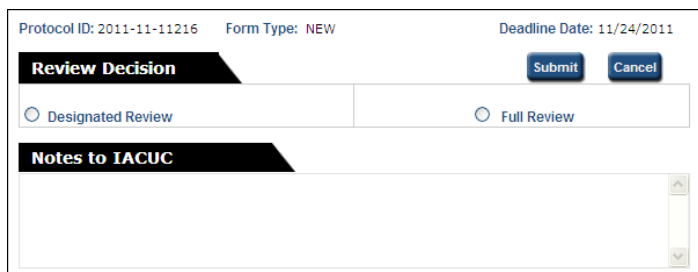
- The DMR call to FCR protocol will be highlighted in pink on the Reviewer Home Page.



- Click on the **Protocol ID** to view the protocol.
- Click on the **Protocol Event** link to continue the review process.
  - The Review Decision pop-up window will open.
  - Click Get Protocol to view the protocol
  - Click on Review Decision to submit a review decision.



- Select either **Designated Review** or **Full Committee** and **Submit**.



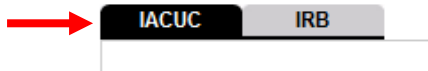
- Select either **Designated Review** or **Full Review**
- Add any **Notes to IACUC (OACU)**
- Click **Submit**

- You can submit **Notes to the IACUC (OACU)** along with your decision.

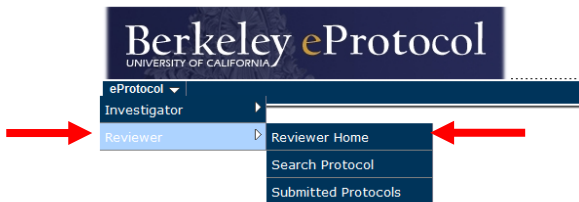
b. If no “Call to FCR” is submitted **within 3 working days**, DMR review will proceed.

### 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>
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.
  - a. 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.

Click on **Protocol ID** to

Click on **Protocol Event** to



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

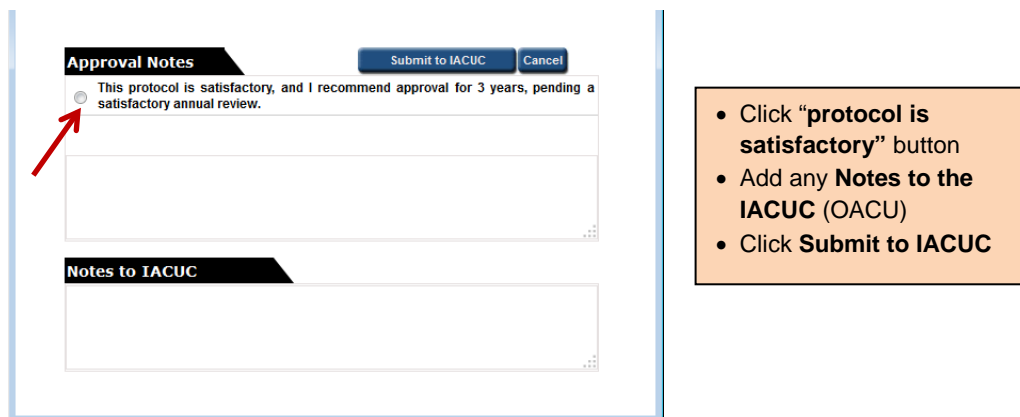
**AMENDMENT**  
Currently there are no Amendment protocols.

**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
  - 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 the radial **"protocol is satisfactory"** button.
  - ii. You can write **notes to the IACUC** (OACU).
  - iii. **Submit to the IACUC** (OACU).



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

eProtocol » Reviewer » [Home](#) » Comments

Protocol ID: [14-08-3780](#) (PI Name)

Review Type: Full Review

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

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

- 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 Manger** (OACU) pop-up window is displayed.
- viii. Add any **Notes to Manager**.
- ix. Click on **Submit to IACUC**.



- 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.

IACUC						
IACUC Member (Protocols for Review)						
NEW						
Role	Protocol ID	Principal Investigator	Title	Protocol Event	Panel	Meeting Date
Reviewer	<a href="#">14-08-3780</a>	Rachel Cameron	Troubleshooting Prof. Hayes - character limits in Study O...	<a href="#">Assigned as Reviewer</a>	ACUC	10/08/2014
NPR	<a href="#">14-04-3724</a>	Richelle Scales	richelle scales music study	<a href="#">Assigned as Reviewer</a>	ACUC	05/14/2014
Presenter	<a href="#">2010-02-711</a>	EMP-FACULTY TEST	This is Testuser protocol	<a href="#">Comments Sent (Cycle 1)</a>	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.

IACUC							
IACUC Member (Protocols for Review)							
NEW							
Role	Protocol ID	Form Name	Principal Investigator	Department Name	Protocol Event	Panel	Meeting Date
Presenter	<a href="#">2011-11-11216</a>	IACUC	Michael Atherton	Biomedical Sciences	<a href="#">Responses Received (Cycle 1)</a>	IACUC	12/04/2011

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.
    - Changes made to the protocol are tracked.
  - 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

**Comments**

Title: BONITAK1 Reviewer: Krall, Bonita

Select Section: Funding

Test Comment

Response Necessary for Approval  
 Suggestion Not Necessary for Approval

Response

Test Response

Recommend for Approval Guidelines Reviewers

Get Protocol Get PDF Write Comment(s) Show All Comments

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

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](mailto:acuc@berkeley.edu)