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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.
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** or **Full Committee** and **Submit**.

   a. 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.
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).

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

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**.

x. After you submit your comments to the IACUC or recommend for approval, 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.
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**.

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