Resubmit a Returned Protocol

> **Important:** A protocol can be created, edited, and submitted by a Principal Investigator or Faculty Sponsor, Co-Principal Investigator, Student or Postdoctoral Investigator, Administrative Contact, or Other Contact. *However, before the protocol can be submitted, the Principal Investigator or Faculty Sponsor must check the appropriate box in the Assurance section.* This requirement exists as an electronic substitute for an ink signature from the Principal Investigator or Faculty Sponsor.

1) Log in to eProtocol with your CalNet ID & password at: https://eprotocol.berkeley.edu

2) Click on the **IRB** tab to see your Investigator Homepage for IRB Submissions.

3) Click on the **Resubmit the Protocol** link in the Protocol Event column.
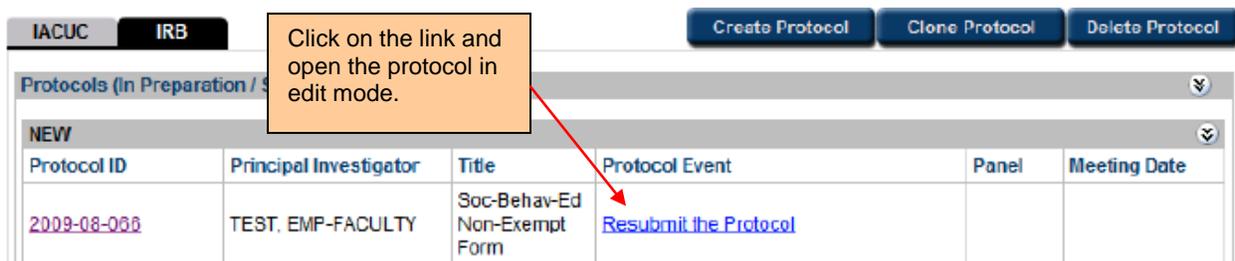
4) A pop-up window will appear asking if you want to open the protocol for editing. Click on **Edit**.

   Note: If there is no edit option, someone else has the protocol open and you must ask them to close the protocol before you will be able to proceed. Only one person can edit a protocol at one time.
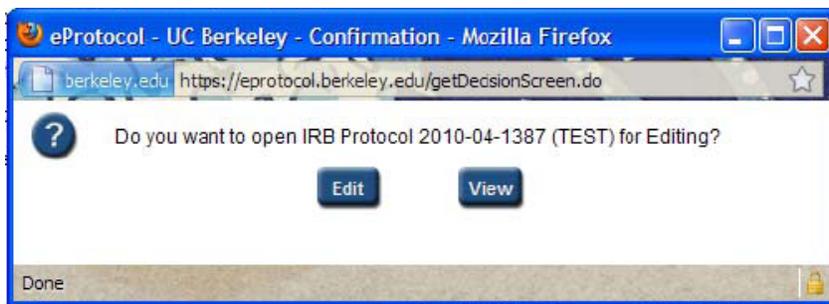
5) To see why the application was returned, click on **Return Notes** in the blue side panel menu. A pop-up will appear with comments from OPHS Staff. Close the popup and make any edits/revisions to the protocol.

6) When ready to re-submit, click on **Assurance** in the blue menu on the left side of the screen. There are different requirements for this section depending on whether the protocol is for research by a Principal Investigator or for research by a Student/Postdoctoral Investigator, as follow:

   o <u>For Student or Postdoctoral research</u>, the Assurance section includes two separate assurance statements: (1) one to be completed by the Faculty Sponsor and (2) one to be completed by the Student or Postdoctoral Investigator. Each party must log in separately, open the protocol application for editing, and check the box for the appropriate assurance statement.

Funding
Protocol Information
Assurance
Print View
Event History

Faculty Sponsor assurance statement

As Faculty Sponsor, I understand that I am responsible for overseeing the protection of the rights and welfare of the human subjects, and adherence to CPHS requirements, federal regulations, and state statutes for human subjects research.

I hereby assure the following:

Faculty Sponsor must log in to check box

1.

2. I have discussed with the Student/Postdoc Investigator how to comply with his or her assurances.

3. I will be available throughout the course of the study to provide guidance and consultation.

☐ **I have read and agree to the above assurances.**

Student/Postdoctoral Investigator assurance statement

As Student/Postdoctoral Investigator, I am responsible for the performance of this study, the protection of the rights and welfare of the human subjects, and strict adherence by all co-investigators and research personnel to CPHS requirements, federal regulations, and state statutes for human subjects research.

I hereby assure the following:

1. The information provided in this application is accurate to the best of my knowledge.

2. All experiments and procedures involving human subjects will be performed under my supervision or that of another qualified professional listed on this protocol.

3. The description of human subjects used in the funding proposal(s) is identical in principle to that contained in this application.

4. The legally effective informed consent of all human subjects or their legally authorized representative will be obtained (unless waived) using only the current, approved consent form(s).

5. If any study subject experiences an unanticipated problem involving risks to subjects or others, and/or a serious adverse event, the CPHS will be informed promptly within no more than one week (7 calendar days), and receive a written report within no more than two weeks (14 calendar days), of recognition/ notification of the event.

6. No change in the design, conduct, or key personnel of this research will be implemented without prior CPHS review and approval, unless the changes are necessary to eliminate an apparent immediate hazard to subjects. Changes made to eliminate hazards to subjects will be reported to OPHS/CPHS via the AE/UP reporting process.

7. Applications for continuation review will be submitted in a timely manner prior to the expiration date to allow sufficient time for the renewal process. I understand that if approval expires, all research activity (including data analysis) must cease until I receive notice of re-approval by the CPHS.

Student/Postdoctoral Investigator must log in to check box.

8. Pa   uests for information about the study will be addressed appropriately.

9. I will promptly and completely comply with a CPHS decision to suspend or withdraw its approval for the project.

10. I will submit a study closure form at the conclusion of this project.

☐ **I have read and agree to the above assurances.**

b) <u>For Principal Investigator research</u>, there is only one assurance statement. The Principal Investigator must log in to check the box.

General Checklist	**Assurance**
Funding	
Protocol Information	As Principal Investigator,, I have ultimate responsibility for the performance of this study, the protection of the rights and welfare of the human subjects, and strict adherence by all co-investigators and research personnel to CPHS requirements, federal regulations, and state statutes for human subject's research.
Assurance	
Check For Completeness	I hereby assure the following:
Submit Form	
Print View	1. The information provided in this application is accurate to the best of my knowledge.
Event History	

2. All experiments and procedures involving human subjects will be performed under my supervision or that of another qualified professional listed on this protocol.

3. This protocol covers the human subjects research activities described in the grant proposal(s) supporting this research, or any such activities that are not covered have been/will be covered by a CPHS approved protocol.

4. The legally effective informed consent of all human subjects or their legally authorized representative will be obtained (unless waived) using only the current, approved consent form(s).

5. If any study subject experiences an unanticipated problem involving risks to subjects or others, and/or a serious adverse event, the CPHS will be informed promptly within no more than one week (7 calendar days), and receive a written report within no more than two weeks (14 calendar days), of recognition/ notification of the event.

6. No change in the design, conduct, or key personnel of this research will be implemented without prior CPHS review and approval, unless the changes are necessary to eliminate an apparent immediate hazard to subjects. Changes made to eliminate hazards to subjects will be reported to OPHS/CPHS via the AE/UP reporting process.

7. Applications for continuation review will be submitted in a timely manner prior to the expiration date to allow sufficient time for the renewal process. I understand that if approval expires, all research activity (including data analysis) must cease until I receive notice of re-approval by the CPHS.

8. Participants' complaints or requests for information about the study will be addressed appropriately.

9. I will promptly and completely comply with a CPHS decision to suspend or withdraw its approval for the project.

10. I will submit a study closure form at the conclusion of this project.

☐ I have read and agree to the above assurances.

7) Once the application is complete, submit the application by clicking on **Submit Form** in the blue side panel menu.

Personnel Information
Vulnerable Subject Checklist
Study Sites
General Checklist
Funding
Protocol Information
Assurance
Check For Completeness
Submit Form
Print View
Event History

8) A pop-up will appear asking if you want to submit. Click on **Yes**.
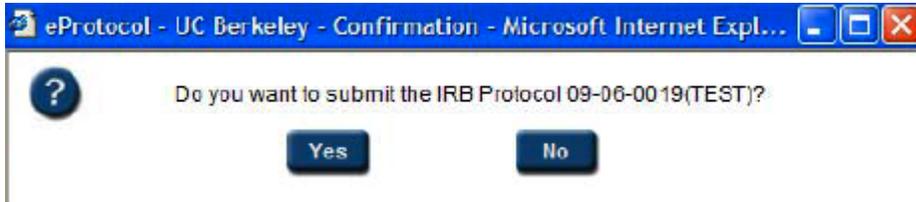
9) The system will then check to make sure that all of the sections in the protocol application have been completed.

  o If any section is incomplete, the protocol will not be submitted and another pop-up will appear including a link to the incomplete section(s); you will need to click on the link to add the missing information, and repeat steps 6 - 8.
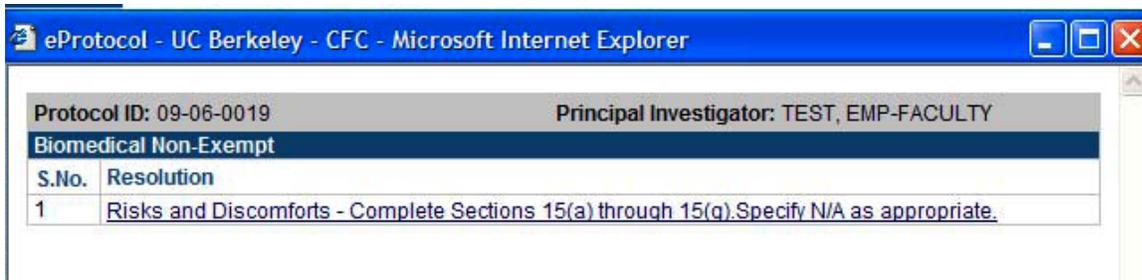
  b) If the protocol application is complete, a message will on appear your Investigator Homepage in bright blue thanking you for the submission and the Protocol Event column will change to read "RESUBMITTED TO IRB."