Amend (Modify) an Approved Protocol

Important: A protocol can be created, edited and submitted by the Principal Investigator (PI), Laboratory Contact, or Administrative Contact. <u>However</u>, ONLY the Principal Investigator can complete two sections of the protocol:

- Only the PI and/or Co-PI of the grant or subcontract can add his or her own SPO Funding information in the **Funding Sources** section of the protocol. The PI of the grant or subcontract must also be listed in the Personnel Information section of the protocol in one of the following roles: Principal Investigator, Laboratory Contact or Alternate Lab Contact.
- Before the eProtocol system will permit the protocol to be submitted, the PI must log into the system and check the appropriate box in the **Certification** section of the protocol, accepting the responsibilities of the PI. This requirement exists as an electronic substitute for an ink signature from the PI.
- 1) All changes to your protocol must be reviewed and approved by the ACUC before being undertaken.
 - a. For additional information, including an appendix with information regarding potential review type based on information added to a protocol, please see the ACUC <u>Policy and Procedures on Protocol Review</u> on the ACUC web site, <u>https://www.acuc.berkeley.edu</u>
 - b. If a protocol is currently undergoing an Amendment (submitted or not), you cannot start the Continuing Review process, and vice versa. Only one review process can occur at a time.

NOTE: The system will not allow simultaneous Amendment and Continuing Review applications for the same protocol. Please begin a Continuing Review application first. If you have <u>minor</u> changes to make, you can include these as part of the Continuing Review. If you have <u>significant</u> changes, however, this may delay your Continuing Review because they may need to be reviewed by the Full Committee or by Designated Member Review (see the <u>ACUC Policy</u> <u>& Procedure on Protocol Review</u>. If you have **significant** changes to make, first submit and obtain approval of the Continuing Review application, then submit an Amendment. If an Amendment Application has already been started, you must withdraw it before eProtocol will allow you to begin a Continuing Review application.

- 2) Log in to eProtocol with your CalNet ID & password at: https://eprotocol.berkeley.edu
- 3) Click on the IACUC tab to see your Investigator Home Page for ACUC Submissions.

IACUC IRB

- 4) From your Investigator Home Page, there are two ways to get to a list of your **approved protocols**:
 - a. Scroll to the bottom of the page; or,

b. Go to the **Investigator Menu** on the upper left side of the page and click on **Approved Protocols**.



5) Click on the **Protocol ID** link of the protocol that you wish to amend/modify.

| Approved Protocols | | | | | | | |
|--------------------|---------------------------|----------------------------|------------------|--------------------------|--------------------|----------------------|-----------|
| Protocol ID | Principal Investigator | Title | Approval Date | Last Approval Date | Expiration Date | Review Decision | Form Type |
| <u>14-07-3748</u> | EMP-FACULTY TEST | Type your study title here | 08/04/2014 | 08/04/2014 | 06/30/2017 | Designated Review | NEW |

6) Select **Start Amendment** from the Approved Protocol Decision menu and click on **OK**.



- 7) To complete the Amendment Form, answer questions 1 and 2, and check all statements that apply in question 3.
- 8) To make changes to the protocol, click on the appropriate section of the protocol that you wish to modify.

| | | Save | Spell Check Help Close | | | | |
|--|---|--------------------------|-----------------------------|--|--|--|--|
| | Click on each section protocol to make cha | | Previous Next | | | | |
| Amendment | | | | | | | |
| Personnel Information | - | | | | | | |
| Species | Amendment | | | | | | |
| Are You Using? | List of Sections (and questions) that have been changed/modified | | | | | | |
| - Funding Sources | If you would like to make changes to the in add/modify a procedure, etc., click on the | | | | | | |
| Protocol Information Certifications | 1. Please provide a brief summary of th | e proposed amendment: | Complete questions 1 & 2 | | | | |
| Return Notes | One behavioral assay procedure was | added to the protocol. | and check all that apply fo | | | | |
| Protocol Notes | | | question 3 | | | | |
| Print View | 2 Diago provido a rationalo for the pro- | posed amondmont: | | | | | |
| Event History | 2. Please provide a rationale for the proposed amendment: | | | | | | |
| Email History | The proposed amendment allows for the collection of neural data during natural behavior in the home cage environment. | | | | | | |
| | A change from non-survival to survival surgery A change that results in greater pain, distress, or degree of invasiveness A change in housing and/or use of animals in a location that is not part of the animal program overseen by the ACUC The addition of a new species A change in the objectives of a study A change in the Principal Investigator (PI) A change that impacts personnel safety A change in compounds or dosage of experimental substances which are fundamentally similar to compounds already approved in the protocol, and are documented in the literature regarding safety and toxicity in the same species A change in compounds or dosage of anesthesia, analgesia, or sedation that are consistent with UCB ACUC guidelines A change in euthanasia method to any method approved in the AVMA guidelines (including UCB ACUC euthanasia guidelines) A greater than (>) 10% increase in the <i>originally</i> approved number of animals of any one species | | | | | | |
| | Changes in funding sources | | | | | | |
| | Updates (Current) | Changes are tracked and | noticeable | | | | |
| | Procedures | after the Amendment is s | | | | | |

a. After you submit the Amendment form, the sections you modified will be listed at the bottom of the Amendment Form, and will be noticeable with track-change tools.

9) You can closeout of the protocol at any time and access it again from your Investigator Home Page. Save the page you are working on before closing the protocol. It will appear in the **Amendment Section** of the Investigator Home Page, just below New Protocols (In Preparation / Submitted).

| AMENDMENT × | | | | | | | | |
|---------------------|---------------------------|--------------------------------------|--------|------------------|-------|--------------|-----------------|--|
| Protocol ID | Principal Investiga | gator Title | | Protocol Event | | Panel | Meeting Date | |
| 14-07-3748 | EMP-FACULTY TES | ULTY TEST Type your study title here | | Yet to Submit to | IACUC | ACUC | | |
| | | | | | | | | |
| CONTINUING REVIEW 😵 | | | | | | | | |
| Protocol ID | Principal Investigator | Title | Protoc | ol Event | Panel | Meeting Date | Expiration Date | |

10) When the Amendment Application is complete and you are ready to submit the application to ACUC/OACU, see the eProtocol Quick Guide <u>Submit a Protocol Application</u>.