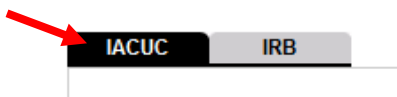


Submitting an Protocol for De Novo Review

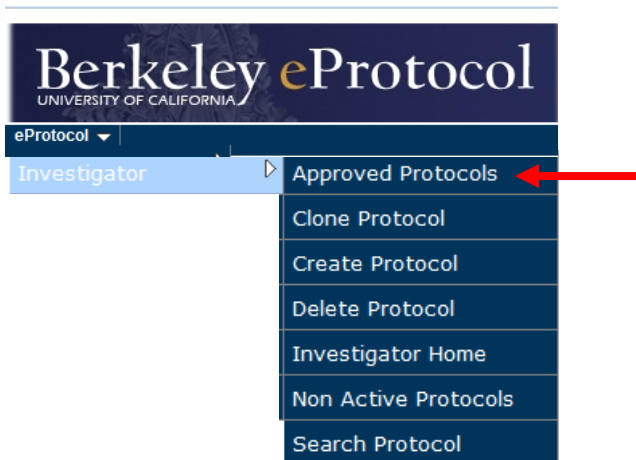
Important: A protocol can be created, edited and submitted by the Principal Investigator (PI), Laboratory Contact or Alternate Lab Contact. **However, ONLY the Principal Investigator can complete two sections of the protocol:**

- Only the 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. Training grants can be added by anyone in the one of the aforementioned roles.
- 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) ACUC is charged with conducting a complete review (*de novo*) of all previously approved projects at least once every three years.
- 2) The PI, Lab Contact and Alternate lab contact receive an email from eProtocol **100 days prior to submission due date** for the *de novo* review.
- 3) **Important:** All changes to your protocol (including, but not limited to, personnel, animal numbers, species, or animal procedures) must be reviewed and approved by the ACUC before being undertaken.
 - a. For additional information, please see the ACUC [Policy and Procedures on Protocol Review](http://www.acuc.berkeley.edu) on the ACUC web site, <http://www.acuc.berkeley.edu>
 - b. If a protocol is currently undergoing an Amendment (submitted or not), you cannot start the *de novo* process, and vice versa. Only one review process can occur at a time.
- 4) Log in to eProtocol with your CalNet ID & password at: <https://eprotocol.berkeley.edu>
- 5) Click on the **IACUC** tab to see your Investigator Home Page for ACUC Submissions.



- 6) From your Investigator Home Page, there are two ways to get to a list of your **approved protocols**:
- 1) Scroll to the bottom of the page; or,
 - 2) Go to the **Investigator Menu** on the upper left side of the page and click on **Approved Protocols**.



- 7) Click on the **Protocol ID** link of the protocol for which you wish to submit for de novo review.

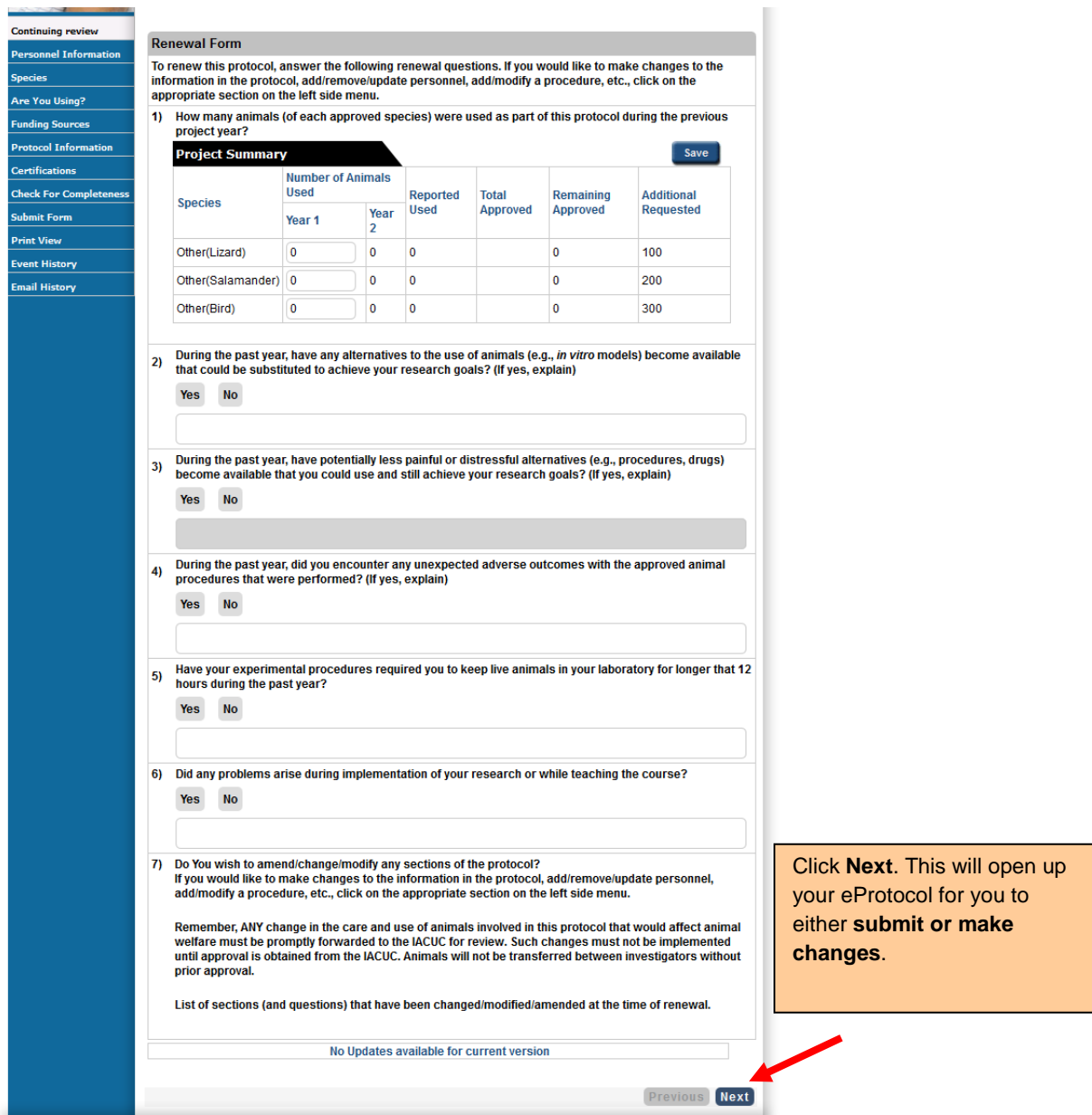
Approved Protocols							
Protocol ID	Principal Investigator	Title	Approval Date	Last Approval Date	Expiration Date	Review Decision	Form Type
14-07-3748	EMP-FACULTY TEST	Type your study title here...	08/04/2014	08/04/2014	06/30/2017	Designated Review	NEW

- 8) Select **Start Continue Review** from the Approved Protocol Decision menu and click on **OK**.

Approved Protocol Decision

Please select any one of the following:

- Open in View Mode
- Protocol Details
- Start Amendment
- Start Continuing review
- Close Protocol

9) Leave the Continuing Review Form blank and click **Next**.


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.

1) How many animals (of each approved species) were used as part of this protocol during the previous project year?

Project Summary Save

Species	Number of Animals Used		Reported Used	Total Approved	Remaining Approved	Additional Requested
	Year 1	Year 2				
Other(Lizard)	<input type="text" value="0"/>	0	0		0	100
Other(Salamander)	<input type="text" value="0"/>	0	0		0	200
Other(Bird)	<input type="text" value="0"/>	0	0		0	300

2) During the past year, have any alternatives to the use of animals (e.g., *in vitro* models) become available that could be substituted to achieve your research goals? (If yes, explain)

Yes No

3) During the past year, have potentially less painful or distressful alternatives (e.g., procedures, drugs) become available that you could use and still achieve your research goals? (If yes, explain)

Yes No

4) During the past year, did you encounter any unexpected adverse outcomes with the approved animal procedures that were performed? (If yes, explain)

Yes No

5) Have your experimental procedures required you to keep live animals in your laboratory for longer than 12 hours during the past year?

Yes No

6) Did any problems arise during implementation of your research or while teaching the course?

Yes No

7) Do You wish to amend/change/modify any sections of the protocol?
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.

Remember, ANY change in the care and use of animals involved in this protocol that would affect animal welfare must be promptly forwarded to the IACUC for review. Such changes must not be implemented until approval is obtained from the IACUC. Animals will not be transferred between investigators without prior approval.

List of sections (and questions) that have been changed/modified/amended at the time of renewal.

No Updates available for current version

Previous **Next**

Click **Next**. This will open up your eProtocol for you to either **submit or make changes**.

10) In updating your protocol, please carefully review all information pertaining to current or planned projects to ensure that it is still accurate before including it in the new protocol. In addition, be sure to delete all obsolete or inaccurate information and or procedures that are no longer in use.

- a. Be sure to **Save** your protocol as you make changes.
- b. ACUC has a number of Pre-filled and Pre-approved procedures which may assist you in submitting your protocol for its *de novo* review. For additional information, please see the eProtocol Quick Guide [Procedures](#) on the ACUC web site, <http://www.acuc.berkeley.edu>.

12) When you are ready to submit your protocol for its *de novo* Review, click on the blue **Certification** link in the left margin.

- a. Only the PI can complete the Certification page by clicking on the check box on the bottom of the page.

13) To submit the form, click on the blue **Submit Form** link in the left margin.

- a. A pop-up window will appear, asking if you want to submit the form. Click **Yes**.
- b. The PI, Lab Contact and Alternate Lab Contact receive a confirmation email when the form is submitted to the IACUC.

Save | Spell Check | Help | Close

Previous Next

Continuing review
Personnel Information
Species
Are You Using?
Funding Sources
Protocol Information
Certifications
Check For Completeness
Submit Form
Print View
Event History
Email History

Certification

As Principal Investigator, I have ultimate responsibility for this study, the protection of animal subjects, and strict adherence by all co-investigators and research personnel to federal regulations, state statutes, and University of California (UC) Office of the President (UCOP) and UC Berkeley (UCB) policies pertaining to animal use in research and teaching.

I hereby assure the following:

- 1) As per the ACUC's [Policy and Procedures on Protocol Review](#), any changes in the care and use of animals involved in this protocol will be promptly forwarded to the ACUC for review. Such changes will not be implemented until approval is obtained from the ACUC. I understand that the ACUC and Institutional Official (IO) have the authority to suspend a previously approved protocol if an activity is performed differently from that outlined in the protocol.
- 2) All procedures involving animal subjects will be performed under my supervision or that of another qualified professional listed on this protocol. Individuals listed on this protocol are qualified or will be trained to conduct procedures involving animals outlined under this proposal as per the ACUC's [Training and Education Policy](#).
- 3) As per the ACUC's [Training and Education Policy](#), all individuals listed on an this protocol have completed the required Collaborative Institutional Training Initiative (CITI) course, "[Investigators, Staff, and Students - Basic Course](#)".
- 4) As per the ACUC's [Animal Occupational Health and Safety Program](#) (AOHSP), all individuals working on this protocol have enrolled in the AOHSP by submitting an [Animal Exposure Questionnaire](#) (AEQ). I understand that further participation in the AOHSP is voluntary unless required by the Occupational Health Physician or if the individual is working with specific species or research material.
- 5) The research proposed herein is not unnecessarily duplicative of previous reported research.
- 6) I ascribe to all of the responsibilities outlined in the ACUC's [Principal Investigator Responsibilities policy](#).


As Principal Investigator, I have read and agree to abide by the above obligations.

Previous Next

Save | Spell Check | Help | Close

Only the PI can complete the **Certification** page by clicking the box at the bottom of the page. Once this is complete, click on **Submit Form** to submit the Annual Continuing Review.

- 14) The de novo Review will appear on the **Continuing Review** section of the **Investigator Home Page** until it is approved. The original protocol number will now have a “-1” at the end, indicating this is a *de novo* submission.



CONTINUING REVIEW						
Protocol ID	Principal Investigator	Title	Protocol Event	Panel	Meeting Date	Expiration Date
14-12-3827-1	PI Name	Test patch 12/5/14 test	SUBMITTED TO IACUC	ACUC		09/30/2017

FINAL REPORT						
Currently there are no Final Report forms.						

Approved Protocols						
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