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.

   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](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**.

![Approved Protocols](image)

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

![Protocol ID](image)

8) Select **Start Continue Review** from the Approved Protocol Decision menu and click on **OK**.
9) Leave the Continuing Review Form blank and click **Next**.

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](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.

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.