De Novo Protocol Renewal Guide

The “Create De Novo” button will appear on the main page of each protocol 90 days before expiration, as long as no other amendment is open, in review, or returned for modifications. If an amendment is currently open, it will need to be approved or withdrawn before the de novo application can be submitted.

After clicking “Create De Novo,” you will be prompted to fill out the progress report.

De Novo Review

- An amendment request includes two parts: the Amendment form and modifications to the Study form
- Only one amendment request is allowed at any given time, i.e. amendment 1 must be approved, denied or withdrawn before amendment 2 can be created

1.0 * Progress Report: Briefly summarize results from the past three years' work and explain how the present application continues this work:

Click “OK” and you will be directed to the De Novo workspace. Like an Amendment, you can further edit the Progress Report by clicking “Edit Amendment,” and edit the protocol submission via “Edit Modified Study.”
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De Novo Updates:

During the renewal of your protocol, you will be asked to update some newly required fields in the protocol form.

(A complete list of system updates, including new procedure types, can be found here.)

Other updates to your protocol may include:

- Experimental Design → Summary of Research
  - 2.0 Specific Aims: You may identify completed Aims. If additional Aims are added and the protocol is funded with a grant, a congruency review will be required to ensure the additional Aims are included within the grant.

- Experimental Design → Experimental Groups
  - You may remove completed Experimental Groups or procedures that you will not perform in the next three-year approval period.

- Experimental Design → Experimental Groups → Basic Group Information
  - 4.0 Total Number of Animals: Animal numbers on a de novo submission should include the number of animals that are currently in-house, plus the number that you plan on using for the next three year approval period. For example, if there are currently 150 mice in-house under the protocol (you can check AOPS for the current number of cages) and you estimate using 1000 in the next three years, you should request 1150 total mice in the de novo submission.
  - 5.0 USDA Pain Category: If you have chosen USDA Pain Category E for an Experimental Group, you must justify why in 5.1

- Experimental Design → Experimental Groups → Procedures and Animal Numbers
  - 2.0 Multiple Survival Surgery: Update the new Multiple Survival Surgery format here in 2.1, 2.2, and 2.3 if applicable.

- Experimental Design → Define Procedure Personnel
  - De novo renewals are a good time to remove any lab personnel who are no longer working on the protocol.

- Experimental Design → Animal Housing and Use
  - Update any applicable housing and animal use locations, especially if lab space has been changed.

- Rationale for Animal Use → Consideration of Alternatives
  - 2.0 Perform a new, updated search for alternatives to USDA Pain Category D or E procedures, if any, used in the protocol.

- Rationale for Animal Use → Consideration of Duplication
  - 1.0 Perform a new, updated duplication search using keywords general to the study.
  - 2.0 Add any conferences or meetings attended in the last three years.

- Study Personnel
  - Add or remove any PI Proxies that need editing and submission rights for the protocol.