

## De Novo Protocol Renewal Guide

The “Create De Novo” button will appear on the main page of each protocol 90 days before expiration, if 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 If an amendment is currently open, it will need to be approved or withdrawn before the de novo application can be submitted. **If withdrawing an amendment, please allow the system to reset for 1 hour prior to initiating the de novo.**

My Home **PI Labs** Animal Operations IACUC Studies Procedures Substances Committee Researcher Profiles R

PI Labs

**Current State**

Approved

Edit IACUC Study

Print Preview

View Differences

Create Amendment

Create De Novo

Study Title	(IS00001862)	
PI:		Full Committee Review:
Date Modified:	6/20/2018 1:15 PM	Meeting:
Original Approval Date:	8/11/2015	Latest Approval Date:
Expiration Date:	8/10/2018	

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graph LR; A[Pre-Submission] --> B[Veterinarian Pre-Review]; B --> C[Coordinator Review]; C --> D[Changes Required]; D --> B; C --> E[Designated Review]; E --> F[Coordinator Determination]; F --> G[Returned for Modifications]; G --> E; F --> H[Review Complete];
```

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- Only one amendment request is allowed at any given time, i.e: amendment 1 must be approved, denied or withdrawn before amendment 2 can be created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:

- Study Identification
  - Title
  - Co-PI **Note:** If the PI of the protocol has changed, please recreate the protocol in the new PI's laboratory.
  - Emergency contacts: Ensure that the mobile phone number for each person is up to date.
- Study Identification, continued: Please address the prompts
  - 1.0 Is this a three year de novo from a paper protocol. **Note:** If renewing with de novo button, it is from an electronic protocol, so the answer would be 'no'.
  - 2.0 Is this a competitive renewal. **Note:** If this is a competitive renewal, we recommend starting a new protocol to go along with the new grant.
- Funding Source: Ensure the funding source is up to date. If awarded through Northwestern's Sponsored Research, please update the funding source utilizing the infoED matching tool.
- Summary of Research
  - 1.0 Lay Summary
  - 2.0 Specific Aims: Identify completed Aims. Update Aims, if applicable.
- Experimental Design → Experimental Groups
  - Remove completed Experimental Groups
- Experimental Design → Experimental Groups → Basic Group Information
  - Review information on page and ensure it is up to date.
  - **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
  - **1.0 Procedures: Review procedures and ensure the desired version is present if multiple versions exist.**
    - Remove procedures that you will not perform in the next three-year approval period.
    - We recommend consulting with a veterinarian on new and existing procedures to ensure that they are up to the current standards of care. Particularly with procedures requiring the use of analgesics.
    - If utilizing Approved Animal Procedures (AAPs), please visit the IACUC website to review the latest protocol directions for use of AAPs and update accordingly. **Note:** Do not to include IACUC document numbers, as those are subject to change with each revision.

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- 2.0 Multiple Survival Surgery: Update the Multiple Survival Surgery questions here in 2.1, 2.2, and 2.3 if applicable.
- 3.0 Number of Animals Justification: Ensure the animal number justification is up to date and the final number matches the total number requested on the Basic Group Information page 4.0 Total Number of Animals.
- 4.0 Sequence and Timing: Ensure the sequence and timing of procedures is up to date and ensure that 1.0 procedures is reconciled with this section.
- Define Procedure Personnel
  - Remove any lab personnel who are no longer working on the protocol to avoid delays in review due to OHS re-enrollment and training requirements.
- Genetically Modified Animals, if applicable
  - Ensure all documents and questions are up to date.
  - Review and update personnel responsible for monitoring and their contact information.
- Identification of Background Strains: Rodent Users Only
  - Ensure background strains are up to date
- Animal Housing and Use
  - 1.0 Animal Housing: Updating any applicable housing locations per the protocol side bar instructions.
  - 2.0 PI Managed Sanitization of Laboratory Equipment: Ensure this question is up to date per the protocol sidebar instructions.
  - 3.0 Animal Use: Ensure all procedures listed in experimental groups are assigned a use space per the protocol sidebar instructions.
- Animal Care Exceptions, if applicable
  - Ensure all prompts are up to date
- Federal Assurances
  - Ensure all prompts are up to date
- Check the PI Acknowledgement box Rationale for Animal Use → Consideration of Alternatives-**USDA Covered Species Only**
  - 2.0 Perform a new, updated search for alternatives to USDA Pain Category D or E procedures, if any, used in the protocol.
- Protocol Attachments
  - Remove any outdated attachments (e.g., expired grant) and add any new attachments (e.g., updated grant) (if applicable).
- Study Personnel
  - Add or remove any PI Proxies that need editing and submission rights for the protocol.
  - Update 2.0 if there are any other personnel that will be associated with the Protocol, if applicable. **Note:** This section is intended for non-animal admin users that are not already associated with procedures, but need access to the protocol.
- Administration of Substances Summary, Hazardous Substances, and Personnel Training Summary are automatically populated pages based on procedures and personnel assignments. These pages are not editable, but are good pages to review and verify that all substances and personnel are properly associated with the protocol.

## FAQ

- **Why am I being asked to update a procedure that I have been using for the past three years without issue?**
  - Standards change over time, and de novo submissions are an opportunity to bring existing protocols up to the current standards. If you have any questions or concerns about changes in veterinary care, please contact a CCM veterinarian.
- **Why am I being asked to update my AAP?**

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- IACUC Approved documents are required to be reviewed every three years, just like protocols. During these reviews, AAPs may change to bring the AAP up to current standards, to clarify protocol entry instructions, and to ensure all necessary information is included in the AAP form (e.g., substances). It is recommended that you check the current version of the AAP on the [IACUC website](#) to see if any changes have been made.