Institutional Animal Care and Use Committee SOP 121

TITLE: eSirius 3G: Submitting a De Novo Review (Renewal)

PURPOSE: To provide guidance to research staff on the submission of a De Novo Review in eSirius3G.

REVIEW/REVISIONS: IACUC Office staff will review and revise this SOP as needed.

PROCEDURES:

- Log into eSirius 3G
- Select the PI you wish to perform the De Novo review for from the pull down list at the top of the screen
- Select the Protocol Management option under the Mailbox header
- Click the De Novo Reviews Due (Renewal) option under the alert section for Protocol Management on the Mailbox to open this tab
- Click on the protocol number hyperlink for your protocol on the De Novo Reviews Due (Renewal) tab. Note: you will be unable to start the De Novo Review process if you have an amendment in progress. Draft amendments should be cancelled and the changes incorporated into the renewal protocol. Amendments in review must complete the review process.
- Complete the progress report field and select a status for the protocol. Save the page and select the Start Renewal button. You may edit the progress report field after you start the renewal if needed.
- The entire protocol is now open for revision. Keep in mind that the text you are looking at is for the past three years. Update so that the information provided covers the work you plan to perform over the next three years.
- Once you have started your renewal protocol, the draft is displayed on the Draft Protocol tab. Click the Draft Protocols option under the alert section for Protocol Management on the Mailbox to reveal this tab.
- You may reenter the protocol by clicking the protocol number hyperlink
- You will need to modify each page of the protocol so that you get a green check mark next to the page name on the Table of Contents
- Attach a full copy of all NIH/PHS grants to the Federal Funding page
- As applicable, attach a new Breeding Addendum to the Breeding page and new Compounding SOPs to the Exceptions page. Forms can be found on the IACUC eSirius page.
- Email the IACUC Office (orcr-iacuc@email.arizona.edu) when the draft protocol is ready for administrative review. Submitted protocols must remain on the Draft Protocols tab until the administrative review process is complete.

After completion of the administrative review process:

- The PI will be required to submit the protocol. This is the only time that the PI must submit a document in eSirius 3G. Click the Submit to IACUC Office option from the Table of Contents inside the protocol document and then the Submit to IACUC button. eSirius will automatically notify the IACUC Office that the protocol has been submitted.
- The eSirius system will send an email to the protocol contacts when there are IACUC review comments to address
  - The renewal protocol will now be on the Protocol/Amendment in Review tab. Click the Protocol/Amendment in Review option under the alert section for Protocol Management on the Mailbox to reveal this tab.
  - Click on the Protocol/Amendment in Review tab and then the protocol number hyperlink to open the protocol. Pages with review comments will be indicated on the table of contents with an icon.
  - Select the first page with review comments
Click on the footnote number in the Review Notes field, or on your original text in the main field, to open a new field named “Changes that have been made in document”. Scroll through the text in this section to locate the matching footnote number from the Reviewer Notes field.

Click on the number associated with the review comment to go directly to the appropriate tab for pages with multiple tabs (e.g.: Surgery; Clinical Signs/Moribundity)

Make the requested changes in the original field (not the review section) or use the review rebuttal option to let the reviewer know why you have not made a modification

Repeat process for all marked pages

The table of contents icon will change to a green check mark when the review comments have been addressed. All pages marked with a review comment must have a green check before the submission can be routed back to the IACUC.

Submit the renewal back to the IACUC using the Submit to IACUC Office page from the table of contents within the protocol. eSirius will automatically notify the IACUC Office that the protocol has been returned.

o The eSirius system will send an email to the protocol contacts when the protocol is approved