OAKLAND
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Institutional Animal Care and Use Committee

Standard Operating Procedure

How to Revise a Previously Approved Application

A revision is any change to an approved protocol. All revisions must be approved by the IACUC. The IACUC recognizes that Principal Investigators (PI) often need to change or revise their project procedures and/or aims after an IACUC approved project has been initiated, and that the approval of these changes should be done in a timely manner. However, due to federal laws and policies, all significant changes to animal use protocols can only be approved after the changes have been reviewed and discussed by the IACUC at a convened meeting. Revisions are classified as either Non-significant Changes or Significant Changes. This distinction does affect how the request for revision is reviewed by the IACUC.

Non-significant Changes - can be approved administratively by submitting the appropriate amendment form to the IACUC Administrator at schofdin@oakland.edu. Some examples are:

• addition or removal of project personnel (except for the PI and responsible faculty member)
• add or change source(s) of animals, as long as the source is an approved commercial vendor
• add or change source(s) in grant funding
• change in project dates, so long as the total project period does not exceed three years

The IACUC Administrator informs the full committee of any administratively-approved revisions at the next convened meeting of the IACUC, and they are listed in the meeting minutes.

Significant Changes - must be reviewed by the full committee.
Some examples include, but are not limited to changes in the:

• objectives of the study
• procedures being performed on live animals
• pain category
• strain of animal
• species
• principal investigator and/or responsible faculty member

Instructions for submitting a request for revision of an approved protocol in RAM
1. Log into RAM 3.0 from the Research web page.
2. At the top of the list entitled "Your Applications" there is a link on the right entitled, "Revise an Approved Application". Click on that link.
3. Select the application you need to revise and then click the **SUBMIT** button.
4. At the bottom of the page, in the list of attachments, you will find the Word file of your application. Open this file and save it to your computer.

5. Make the necessary changes/revisions to this document. Indicate all changes/revisions by making them in a different color of type so that they are distinct from the original protocol and any previous changes/revisions. If any personnel, procedures, or other parts of the document are to be deleted, they are not to be removed, but marked with a strikethrough (~~example~~).
6. In the header of the document, write the previous IACUC project reference approval number followed by the word "revised" and the date of the current revision
7. After completing the revisions, attach the revised document to the previously approved application in RAM.
8. Also attach a Cover Letter, similar to that used when addressing manuscript publications, that summarizes the requested revision and lists them by Item number. (This will aid the IACUC in understanding your request for revision.)
9. After attaching the revised application and cover letter, click on the **SUBMIT** button at the bottom of the page.
10. Every time an application is revised or modified, a hard copy of the application must be submitted to the IACUC Administrator. This hard copy must include an Assurance/Signature Page that is signed and dated by **both** the Principal Investigator or responsible faculty member, and their department chair or director.

IACUC Review

<u>Procedure for review of requests for Significant Changes:</u>
Request for revisions that involve Significant Changes must be submitted to the full committee for review. According to Oakland University's Public Health Service (PHS) Policy Assurance Statement, all requests for revisions involving Significant Changes must be reviewed and approved using the same process by which new applications are reviewed.

If you need assistance with this process please contact the IACUC Administrator at: 248-370-4440 or schofdin@oakland.edu