

University of Louisville
Institutional Animal Care and Use Committee
Policies and Procedures

Modification of an Approved *Proposal*

Policy: Any changes to animal use beyond what is described in an IACUC-approved *Proposal to Use Laboratory Animals in Research and Teaching* (“*Proposal*”) are prohibited. Alterations to animal use must be reviewed and approved before occurring.

Rationale: The IACUC is responsible for ensuring the humane and ethical use of animals. The *Proposal* provides the IACUC the ability to understand and sanction the use of animals in a research, teaching, or testing project. As such, the IACUC-approved *Proposal* serves as a contract between the committee and the Principal Investigator. Changes to animal use must therefore be reviewed as an amendment or modification of an existing *Proposal*.

Procedures, Guidelines, and Exceptions:

1. Submission

All changes to approved *Proposals* must be easily distinguishable from the previous version. This is automatically performed for *Proposals* originally submitted in iRIS through a comparison report. All changes should be summarized using the iRIS form titled “Click Here to Modify an Approved IACUC Protocol” and a brief rationale for making the changes should be provided.

2. Administrative Changes

Proposal changes limited to: a) title, b) funding source(s), c) typographical-type errors (misspellings, printing errors, *etc.*), d) contact information updates, e) change in personnel or their roles, other than Principal Investigator changes, or f) a new procedure location within the animal program overseen by the IACUC, will be reviewed and approved administratively by the IACUC Office.

3. Project Participant Changes

Requests to add or remove Project Participants are submitted to the IACUC Office by completing the “Add/Remove Personnel” form in iRIS. This is accomplished by selecting the study to which the personnel are being added or removed and selecting “Click here to add or remove personnel” under IACUC forms. Changes in personnel will be approved once mandatory training requirements are fulfilled.

Requests to change the roles (e.g., adding new procedures to a Project Participant's responsibilities) of currently approved Project Participants are submitted to the IACUC using the iRIS form titled “Click Here to Modify an Approved IACUC Protocol.” The Project Participants section of the protocol should reflect all procedures an individual will perform. Changes in participant roles will be approved once the IACUC Office has verified appropriate training and experience for the assigned procedures.

4. Significant Changes Handled Administratively

The IACUC has determined that the following significant changes may be processed administratively by the IACUC Office without further review or consultation:

- a) Increase in animal numbers of mice of the genus *Mus* and rats of the genus *Rattus* of not more than 25% or 500 animals, whichever comes first, of the last approved allocation through designated or full committee review, as long as the study objectives remain unchanged; the animals being added cannot be in Pain Class E (Formerly Class III). Note: requests for additional animals for a new experiment that is not described in the approved protocol *cannot* be handled administratively.
- b) Changes in strain of previously-approved mice of the genus *Mus* and rats of the genus *Rattus*, provided that the strain does not have potential health problems related to phenotype. The addition of genetically modified strains may require Institutional Biosafety Committee (IBC) oversight.

5. Reviewer Assignment and Designated Review

The IACUC Chair (or designee) will serve as the Designated Reviewer for all other requests to modify approved *Proposals*. The veterinarian and/or the Chair may ask that additional committee members review the *Proposal* when appropriate. Requests for modification *that do not alter the pain/distress classification* will be reviewed by a veterinarian and the Designated Reviewer. Requests for modification that increase the pain/distress classification will also be assigned to a Reviewer Consultant. The review and approval process will continue as per a new *Proposal*.

6. IACUC Activity Report and Requests for Full Committee Review

Except for Administrative and Project Participant Changes, modification requests are included in the *IACUC Activity Report*. The report includes the request summary or cover letter, and is forwarded to all members of the IACUC. Any committee member may request, download, or review the complete *Proposal* should additional information be desired. Furthermore, any IACUC member may request Full Committee Review (FCR) of any request to modify an approved *Proposal*. Once requested, final committee action must await FCR.

Committee members are allowed three days following submission of the IACUC Activity Report; lack of a response within the three days is considered acceptance of a *Proposal* for Designated Review.