INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) Guidelines for Amendments and Other Protocol Changes

Investigators may wish to make changes to approved applications during the three-year protocol approval time. These changes are handled in a variety of ways and depend on the type of change being requested. Some changes are handled via an email to the Office of Animal Care and Use (OACU), while others require the submission of an amendment or review by an authorized veterinarian. Amendments requesting the addition of personnel, a change in an individual’s role on the protocol or the addition of specific techniques are handled directly by the OACU staff and are not sent to the IACUC for review. Significant changes to an IACUC approved protocol, defined as changes that negatively impact animal welfare, or have the potential to negatively impact animal welfare, are sent electronically for Designated Member Review (DMR) to a Designated IACUC reviewer, a DLAM veterinarian (for consultation), and all members of the IACUC. Any IACUC member can request a Full Committee Review (FCR) of the amendment to be conducted at the next convened IACUC meeting or the submission of a new protocol instead of an amendment. Alternatively, some significant changes are handled administratively according to IACUC-reviewed and -approved policies in consultation with a veterinarian authorized by the IACUC. The veterinarian may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC-reviewed and -approved policies.

1. Application Changes Handled by Email

Principal Investigator (PI) submits an email to iacuc@med.unc

- Termination of protocol(s)
- Removal of personnel [include full name, PID number and relevant protocol number(s)]
- Change in animal housing location - between buildings only, not rooms within same building [indicate new housing location, old location and protocol number(s) for which changes are requested]

2. Significant Changes to an Approved Application Requiring the Submission of an Amendment

Significant Changes handled by DMR

- Addition of new procedures
- Change in specific study objectives
- Addition of rodent strains that have significant health phenotypes
- PI transfer from one qualified UNC-CH faculty member to another

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• Change(s) in the degree of invasiveness of a procedure or in the degree of pain or distress an animal may experience (Note: changes to painful/distressful procedures involving USDA covered species require an updated literature search)
• Unanticipated or marked increase in clinical signs or animal deaths
• Addition of a non-survival or survival surgery when the original application does not include surgery (assessed case-by-case to determine need for FCR)

3. Significant changes to an Approved Application Which Requires Administrative or Veterinary Review and Inclusion in the Application

Significant changes handled by the OACU staff or IACUC Chair

• Addition of qualified personnel (other than change in PI)
• Addition of a qualified UNC-CH faculty collaborator
• Addition of personnel technique(s)
• Addition of a specific role for already approved personnel (e.g., Laboratory Animal Coordinator, surgeon, etc.)
• Increase in animal numbers not exceeding 25% of originally approved number (does not apply requests for a change in animal species or for amendments with changes in study objectives or health status of the animals or for which additional procedures are included)

Significant Changes handled administratively according to IACUC-reviewed and -approved policies in consultation with an authorized veterinarian

• Changes in the use of anesthetics, analgesics, sedatives/tranquilizers (drugs must be listed in the IACUC-approved drug formulary), or experimental compounds
• Changes in euthanasia to any method approved in the 2013 AVMA Guidelines for the Euthanasia of Animals
• Changes in the duration, frequency, type, or number of procedures performed on an animal
• Addition or change of a collaborator or an approved core facility and any associated changes in housing location, or location where procedures will be performed

4. Significant Changes Requiring Submission of a New Protocol

Changes that require the submission of new protocol and FCR by the IACUC at a convened meeting

• Change in animal species (exception: when multiple species [e.g., fish, wild birds] are described in the protocol, additional species can be requested via an amendment)
• Change in overall purpose of a study
• Greater than 25% increase in the number of animals indicated in the original approved application (handled on a case-by-case basis)