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 approval time. These changes are handled in a variety of ways depending on the change being requested. Some changes can be handled via an email to the Office of Animal Care and Use (please see descriptions below), while others require the submission of an amendment. 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 Office of Animal Care and Use and are not sent to the IACUC for review. In contrast, amendments requiring changes in experimental procedures or those requesting the addition of animals are sent electronically to a Designated Reviewer (determined by the IACUC Chair), a DLAM veterinarian, and all members of the IACUC committee. Although the Designated Reviewer and a DLAM veterinarian conduct a Designated Member Review (DMR) of the amendment, 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.

Application Changes Requiring No Amendment

Changes handled by email to iacuc@med.unc
- Termination of protocol(s)
- Removal of personnel [include full name, PID number and relevant protocol number(s)]
- Change in housing location - between buildings only [indicate new housing location, old location and protocol number(s) for which changes are requested]

Application Changes requiring an Amendment

Changes handled by Office of Animal Care and Use (OACU) review
- 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 (Laboratory Animal Coordinator, Surgeon, etc.)

Changes handled by IACUC Review
- Addition of new procedures
- Increase in animal numbers not exceeding 25% of originally approved number
- Addition of rodent strains/sexes that have significant health phenotypes

Updated 8/28/02, Revised 2/25/04, Revised 11/18/05, Revised 11/13/09; Revised 2/11/10, Revised 11/12/2010, Revised 09/2013, Revised 2/10/15
• Addition of drug(s) or agent(s) or significant changes in dosages or changes to the route of administration
• Addition of sample collection times
• Change in the euthanasia method or the secondary, physical method used to ensure death
• Change of the anesthetic or analgesic agent (must be an approved regimen for the species)
• Investigator transfer from one qualified UNC-CH faculty member to another
• Change(s) in the degree of invasiveness of a procedure or in the degree of pain or distress to an animal (Note: changes to painful/distressful procedures involving USDA covered species require an updated literature search, keywords, and search date)
• Change in the duration, frequency, or number of procedures performed on an animal
• Addition or change of a core facility and any associated changes in housing location, or location where procedures will be performed
• Unanticipated marked increase in clinical signs or proportion of animal deaths

Changes Requiring Submission of a New Protocol

Changes that require the submission of new protocol and review by the IACUC at a convened meeting
• Change in animal species
• Change in purpose or specific aim of study
• Addition of survival surgery (when the original application does not include survival surgery)
• Increase in the number of animals required that exceeds 25% of the original approved application (handled case by case)