Policy # BP-26-2018

Policy Title: Modifications to Approved Animal Activities

Policy: Principal Investigators (PIs) are required to submit for approval any proposed change (modification) to approved protocols prior to implementing the change. The IACUC will review the request to ensure that the modification is in accordance with the Public Health Service (PHS) Policy, United States Department of Agriculture Guidelines (USDA), the Animal Welfare Act (AWA), the Guide for the Care and Use of Laboratory Animals (Guide), and UConn IACUC approved guidelines. The Chair will determine whether a proposed protocol change is minor or significant, and if significant, will consult with the veterinarian to decide whether the change can be handled administratively via Veterinary Verification/Consultation (VVC), or whether it needs to be distributed to the IACUC for review. A list of protocols in which changes were approved is presented to the IACUC at the next regularly scheduled meeting.

A. Types of Modifications:
   a. Administrative/Personnel Changes: These changes can be reviewed and implemented by IACUC Office staff. Examples include but are not limited to:
      - Personnel Changes - other than Principal Investigator
      - Title Changes
      - Funding Changes
      - Correction of typographical errors
      - Correction of grammar
      - Contact information updates
      - Investigators may use fewer animals than approved.

   b. Minor Protocol Changes: The minor changes described below may be approved by the Chair and/or the Attending Veterinarian. Examples include but are not limited to:
      - Change in strain – same species
      - Change in sex of animals used in project
      - Change in vendor
      - Change in room where procedure is conducted
      - Changes of less than 10% in the approximate number of animals used of mice of the genus *Mus* and rats of the genus *Rattus* that are bred for use in research only
      - Some changes in route of administration of a compound
      - Addition of a non-invasive procedure

   c. Significant Protocol Changes: Significant changes described below, must be approved by FCR or DMR. Examples include but are not limited to:
      - Change from nonsurvival to survival surgery
      - Modification of survival surgery procedure
      - Change in procedures resulting in greater pain, distress, or degree of invasiveness
      - Change in housing and/or use of animals in a location that is not part of the animal program overseen by the IACUC
      - Change in species
      - Change in study objectives
      - Change in Principal Investigator (PI)
      - Changes that impact personnel safety
      - Increases in the number of animals
      - Change in age of animals already approved for the study
      - Change in restraint of conscious animals
• Change to Pain Category E

d. **Veterinary Verification/Consultation (VVC):** The specific significant changes described below may be handled administratively in consultation with a veterinarian authorized by the IACUC. The veterinarian is not conducting DMR, but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and approved policy or standard operating procedure (SOP) is appropriate for the animals in the circumstance. Consultation with the veterinarian must be documented. 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 or SOPs. This includes changes in:
  - Anesthesia, analgesia, sedation, or experimental substances
  - Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals
  - Duration, frequency, type, or number of procedures performed on an animal.

B. **Modification Procedure:** When initiating a modification, the PI should contact the IACUC business office in order to obtain the currently approved Word version of the document(s) that need to be modified. The PI should then use the track changes feature of Word to make the necessary changes directly to the document(s) as appropriate. The revised documents are then submitted by email to the IACUC business office at iacuc@uconn.edu, and entered into the review process.