



A. PURPOSE

To ensure that all minor and major protocol changes are approved by the IACUC prior to implementation by the investigator.

B. GUIDELINES

1. If the Principal Investigator (PI) wants to make a change to a currently approved protocol, a request for protocol modification or amendment is submitted. Significant modifications, including the addition of a new species, must relate directly to the scope of the approved protocol. If not, a new protocol must be submitted.
2. Requests for protocol modification or amendment are reviewed for congruency with IACUC approved standards by Animal Welfare Program Staff (administrative review; AR) or UAC veterinary staff (Veterinary Verification and Consultation; VVC) depending on the type of modification; or undergo Designated Member Review (DMR) by at least one IACUC member as assigned by the IACUC Chair, or are reviewed at a fully convened IACUC committee meeting (FCR). Based upon the type of review, the amendment may be implemented based on verification of congruence with IACUC approved standards (AR, VVC), approved (DMR, FCR), may require modifications in order to secure approval or verification (AR, VVC, DMR, FCR) or approval may be withheld (FCR only).
3. Examples of common protocol modification or amendment requests reviewed by one of the methods described above:
 - a. Request to transfer protocol ownership between PIs
 - b. Changes to the protocol title
 - c. Addition or removal of protocol personnel. Note:
 - i. Requests must be submitted by an individual listed as a current protocol participant
 - ii. IACUC Program Staff confirms that the individual(s) to be added to the protocol meets the minimum requirements for inclusion on a protocol as described in IACUC Guidance 124.
 - iii. Personnel lacking minimum requirements are not added to a protocol until all certification, training and occupational health program enrollment has been verified
 - d. Addition or removal of protocol funding
 - e. Addition of animal numbers or species
 - f. Modification of surgical and non-surgical procedures
 - g. Changes to anesthetic regimen, post-operative care, palliative treatment, euthanasia
 - h. Changes to non-UAC housing location
 - i. Request for 12 hours (or more) housing in a laboratory space for USDA regulated species or 24 hours (or more) for non-USDA regulated species

C. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION

- I-IC-SOP-500 Review and Approval of Significant Changes to Animal Activities
- I-IC-GU-124 Protocol Personnel Participation Requirements
 - [IACUC Submission Flowchart - Simplified](#)