TITLE: Review and Approval of Significant Changes to Animal Activities

PURPOSE: To describe the procedure for establishing and using IACUC-reviewed and -approved policies/procedures for verification of significant changes to animal activities

REVIEW/REVIEWS: The IACUC will review and approve this SOP every six months. Modifications may be made at any time by full committee review (FCR) or designated member review (DMR). Updates to internet URLs or Unit names can occur without FCR/DMR.

DATE OF LAST REVIEW: 11/5/2015

PROCEDURES:

As per PHS Policy and the Animal Welfare Act, significant changes to animal activities must be reviewed and approved by full committee review (FCR) or designated member review (DMR).

NOT-OD-14-126 provides guidance on the significant changes which must be reviewed and approved by FCR or DMR:

- Change from non-survival to survival surgery
- Change resulting in greater pain, distress, or degree of invasiveness
- Addition of a satellite animal facility or location not part of the Animal Care and Use Program
- Change in species
- Change in study objectives
- Change in Principal Investigator
- Change that impacts personnel safety (see below)
- Change that affects the scientific aim or scope

However, OLAW (and the USDA) allows IACUCs to establish and use IACUC-reviewed and -approved policies/procedures:

- To define what it considers a significant change (other than listed above)
- To establish a mechanism for determining significance on a case-by-case basis (in accordance with PHS Policy)

The IACUC, either by FCR or DMR, will establish SOPs (500 level SOP) that specifically identify the types of significant changes to animal activities that are suitable for a Request for Change.

Drug formularies:
All clinical veterinary drugs, doses and/or equivalencies referenced in a 500 level SOP use one of the following formularies:

- C.T. Hawk and S. Leary, 2005, Formulary for Laboratory Animals, 3rd edition
- D.R. Lee and C.J. Doane, Association of Primate Veterinarians Formulary
- R. Fish, P.J. Danneman, et al., 2008, Anesthesia and Analgesia in Laboratory Animals, 2nd edition
- University (of Arizona) Animal Care Drug Formulary

When a drug, dose, route or species is not referenced in one of these formularies (e.g., buprenorphine SR), a UAC veterinarian will use their knowledge and professional judgment to verify that drug, dose and/or route is efficacious or does not negatively impact the health and welfare of the animal.
Request for change:
If a proposed change is submitted, IACUC Program staff will determine if the change meets one of the criteria in a 500 level SOP. If yes:

- The IACUC Program staff work with the submitter to accurately describe the requested change
  - Multiple requests may be submitted on the same Request for Change form
  - This may include attachments, such as compounding SOPs or breeding addenda
- If the IACUC SOP does not directly impact animal welfare (IACUC SOP 502, 503, part of 504), IACUC Program staff are responsible for verification
- If the IACUC SOP directly impacts animal welfare (500 level SOPs other than those listed above), IACUC Program staff routes the request to a UAC veterinarian for consultation, who can choose to:
  - Verify the change
  - Request modification prior to verification
  - Convert to an amendment, which is routed for FCR/DMR by the usual procedure
- All decisions are documented on the Request for Change form and returned to the IACUC Program Office
- If a hazard is identified, the Request for Change will be routed to Research Laboratory Safety Services (RLSS; see below)
- Once the change is verified, IACUC Program staff will notify the submitter that they can implement the change immediately, or conditionally (e.g., pre-inspection of a lab location; completion of training)
- Any documentation related to the request for change is added to the protocol file

Definition of “change that impacts personnel safety” and procedures when hazards are identified:
All protocols listing hazards undergo review by RLSS. RLSS are then responsible for ensuring safe use of these hazards. For the purpose of this SOP, a change that would impact personnel safety is interpreted to mean a change that significantly impacts personnel safety. IACUC SOP 501 describes Requests for Change that involves hazards.

Review and approval of IACUC SOPs:
All IACUC SOPs that fall under this SOP (500 level SOPs) will undergo IACUC review and approval at least every six months, generally as part of the semi-annual program review. However, new SOPs or modifications to existing SOPs may be made at any time by full committee review (FCR) or designated member review (DMR).

JUSTIFICATION:

NOT-OD-14-126 Guidance on Significant Changes to Animal Activities describes the types of animal activities where the IACUC has the authority to establish and approve internal policies/procedures for the review and approval of protocol amendments.

USDA agreement with NOT-OD-14-126: http://grants.nih.gov/grants/olaw/educational_resources.htm#a_08212014