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Washington University in St. Louis

Review Processes for Protocol Amendments

IACUC Policy:

Administrative Review: The IACUC has determined that the following changes are minor and may be reviewed and approved administratively by the IACUC office staff. Amendments are approved after verification that all training and occupational health requirements are completed.

- Funding changes
- Personnel addition or modification for use of non-USDA covered species or controlled substances
- Correction of typographical errors
- Correction of grammar
- Updates to personnel info or training
- Change/addition of DCM housing location
- Change/addition of previously approved animal use location
- Increase of 30% animal numbers in non-USDA covered species, no new experiments. The 30% eligible number is calculated from the current total number approved.

Veterinary Verification and Consultation (VVC): The significant changes listed below may be handled administratively in consultation with a DCM veterinarian. The veterinarian is not conducting Designated Member Review, but is serving as a subject matter expert to verify that the proposed change is consistent with all applicable IACUC approved policies and is appropriate for the species.

- Personnel changes for individuals handling USDA covered species
- Change of anesthesia or sedation agent when consistent with IACUC policy or references listed below
- Change of analgesia agent when adequate pain relief is provided and when consistent with IACUC policy or references listed below
- Change of any euthanasia method approved in the current version of the AVMA Guidelines for the Euthanasia of Animals. If methods are approved with conditions, the veterinarian confirms conditions are met. If methods require additional or specialized training, personnel have sufficient experience or have completed the necessary training
- Change in the duration of an approved procedure or experimental timeline by up to 100%. For example, an experiment originally approved to observe animals for 2 weeks may be extended to up to 4 weeks. A 30 minute imaging session may be extended to 60 minutes. If the extension of the procedure or experiment would increase the adverse clinical consequences, the modification must be reviewed by DMR or FCR.
- Change in the frequency or number of an approved procedure by up to 100%. For example, if a protocol is approved to image once a week, an increase to imaging twice a

week could be approved via VVC. The veterinarian will verify that the increase in frequency is not expected to increase the clinical consequences to the animal.

- Increase of 10% animal numbers for USDA covered species, no new experiments. The 10% eligible number is calculated from the current total number approved.
- Change to post-procedure monitoring program (drugs and/or non-pharmaceutical interventions for medical treatment) if the following conditions are met:
    - Drugs and dosages must be selected from current veterinary formularies and not used for experimental or research purposes. For example, anticoagulative therapy following surgical device implantation could not be added if the experimental goal of the study was to compare various anticoagulative therapy regimens following surgery.
    - Non-pharmaceutical interventions may include supplemental warmth, fluids, phototherapy, physical therapy, or dietary supplements.
    - Surgical interventions are not eligible for approval via VVC
- Experimental substances
    - Changes in the dose, route, frequency, or volume of approved substances administered to animals may be approved via VVC
    - This includes administration via special diets or modified water
    - The veterinarian will verify that the proposed changes are appropriate for the species, substance, and route selected
    - New experimental substances to be administered will be reviewed by DMR or FCR

Designated Member Review (DMR) and Full Committee Review (FCR): All other significant changes, including addition of satellite housing, species, surgery, hazards, SOP exemptions, and changes to the Principal Investigator, will be reviewed by DMR or FCR.

Procedures:

The review processes for Administrative Review and VVC are described below. At any stage of the review process, the reviewer or administrator may request the next level of review.

1. **Administrative Processing**. Changes and corrections as outlined above submitted through the electronic protocol management system or by emailing the appropriate form and supporting documentation. Amendments consistent with administrative review criteria will be processed and approved by members of the IACUC Administrative Staff.

2. **Veterinary Verification and Consultation (VVC)**. Amendments are submitted through the electronic protocol management system. Amendments eligible for VVC will be routed to an appropriate Division of Comparative Medicine veterinarian in the electronic system for documentation of veterinary consultation. Proposed changes to any analgesic or drug regimen(s) must follow the IACUC approved Analgesic Guidance for Rodent Procedures or be consistent with the references listed here. Proposed regimens that do not follow the applicable approved guidance, IACUC policy, or formulary must be referred to DMR or FCR review.

Sources of adequate documentation for the verification of proposed changes to anesthesia, analgesia, or sedation agents may include:

- Published veterinary formularies (such as, but not limited to)
  - Exotic Animal Formulary [James W. Carpenter]
  - Formulary for Laboratory Animals [Hawk, Leary, Morris]
  - Plumb's Veterinary Drug Handbook [Donald C. Plumb]
  - Association of Primate Veterinarians Formulary [Lee, Doane]
  - Anesthesia and Analgesia in Laboratory Animals [ed. Kohn, Wixson, White, Benson]
- Research Institution websites
  - UCSF: http://www.iacuc.ucsf.edu/Proc/awDosages.asp
  - UMN: https://www.researchservices.umn.edu/services-name/research-animal-resources/research-support/guidelines/anesthetic-agents
- Peer Reviewed Publications
- Expert Consultation (documented)
- USDA Animal Care Resource Guide and Policy Manual

3. **Committee review**. Proposed protocol amendments that may have an impact on animal health and well-being are considered significant changes. Committee review of significant changes will be conducted using one of the two approved methods—Full Committee Review or Designated Member Review.

References:

1. Public Health Service. Policy on Humane Care and Use of Laboratory Animals (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).

2. National Institutes of Health. Guidance on significant changes to animal activities. Notice NOT-OD-14-126. (National Institutes of Health, Washington, DC, 26 August 2014).

3. Interpreting guidance on significant changes. Silverman, J. Lab Animal 44:85-88. 2015 http://grants.nih.gov/grants/olaw/references/laban44_03_0315.pdf

4. Animal Welfare Regulations (9 CFR 2.31 (d) (1) (i)- (iv))