Subject: Amendment Review Process

BACKGROUND

This Standard Operating Procedure (SOP) provides a detailed description of procedures for amendment review followed by the IACUC.

IACUC Procedure

Before making any changes to a protocol, the Principal Investigator (PI) must submit an amendment request via email or eProtocol depending on the format of the original protocol.

The following language has been adapted from the Office of Laboratory Animal Welfare – Significant Changes to Animal Activities:

 Significant Changes:

1. Significant changes described below (a.-h.), must be approved by Full Committee Review (FCR) or Designated Member Review (DMR), including changes:
   1. from non-survival to survival surgery;
   2. resulting in greater pain, distress, or degree of invasiveness;
   3. in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
   4. in species;
   5. in study objectives;
   6. duration, frequency, type, or number of procedures performed on an animal;
   7. an increase in previously approved animal numbers;
   8. in Principal Investigator (PI); and
   9. that impact personnel safety.

2. Specific significant changes described below (a.-b.), 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 is appropriate for the animals in this circumstance. Consultation with the veterinarian will 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. This includes changes in:
   a. anesthesia, analgesia, sedation, or experimental substances;
   b. euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals.

3. A significant change that may be handled administratively in consultation with an IACUC reviewer is an increase in previously approved animal numbers if the animals being added are in USDA category B.

Upon receipt of an amendment request, a member of the IACUC administration office will determine if the proposed change is significant based on the criteria above. If the amendment request falls into category 2 (above) a veterinarian serving as a subject matter expert will be consulted regarding the proposed change and may recommend that it be approved administratively. If the proposed change falls into category 3 (above) the IACUC office will consult with the Chair (or designee) who may recommend that it
be approved administratively. If there is ever a question as to whether or not a proposed change is significant the Chair (or designee) is consulted.

The Committee is polled as to whether or not an amendment is appropriate for Designated Member Review (DMR). The Committee at large is then allowed a minimum of 24 hours to consider the amendment. If there are no objections to DMR the amendment can be reviewed using that method, as described in the Designated Member Review SOP.

Other Changes:

Changes that may be handled administratively are:
1. changes in personnel, other than the PI. (IACUC Administration Office staff reviews all personnel amendments to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs, and meet all other criteria required by the IACUC.)
2. correction of typographical errors
3. correction of grammar
4. contact information updates

NOTE: Investigators may use fewer animals than approved. This does not require IACUC approval, notification, consultation, or administrative handling.