

Title: Administrative Handling and Veterinary Verification and Review of Animal Care and Use Amendments IACUC Policy P-0011-01

Approval Date: June 23, 2015

Authorized by: Institutional Animal Care and Use Committee, Office of Research Compliance

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## 1. Purpose

In accordance with the Office for Animal Laboratory Welfare (OLAW) Notice NOT-OD-14-126, *Guidance on Significant Changes to Animal Activities*<sup>2</sup>, August 2014, this policy is intended to address the types of protocol modifications that will be allowed to be reviewed and approved by designated administrative or veterinary staff.

## 2. Procedures

- A. Amendments must be submitted using the IACUC Amendment Form in the electronic submission system.
- B. The following amendment types are allowable by Administrative Handling:
  - i. Personnel changes (except Principal Investigator);
  - ii. Changes in Title or Funding Agency
  - iii. Modifications to increase animal numbers for species already approved, provided that:
    - a. The modification does not alter the scope or purpose of the study.
    - b. The modification does not request a change in humane use category.
    - c. The modification must be approved by designated staff members with the expertise required to make these decisions.
    - d. The changes in animal numbers must be justified under the original rationale or an acceptable justification related to the original rationalemust be provided.
    - e. If the administrative reviewer has any uncertainty regarding changes in scope, purpose or rational, the amendment must be sent to the committee for review.
- C. The following amendment types are allowable by Veterinary Verification and Consultation:
  - i. Modifications that request the addition of procedures within the scope of IACUC approved guidelines, provided the addition of those procedures willnot:
    - a. Adversely affect the health or welfare of animals or staff.
    - b. Cause a change in the humane use category.
    - c. Cause a change in the scope of the study.
    - d. These modifications require approval by designated veterinary staff with the experience appropriate to make these decisions.
    - e. If the veterinary reviewer has any uncertainty regarding changes in



scope, purpose or rationale, the amendment must be sent to the committee for review.

- ii. Modifications that request the addition of routine or minor procedures that would positively affect the health or welfare of animals.
  - a. Procedures must not cause a change in the humane use category.
  - b. Procedures must be approved in consultation with designated veterinary staff.

#### 3. Exclusions and Limitations

- A. No modifications to protocols that contain USDA covered species are allowable under this policy.
- B. No modifications to protocols that change the scope or purpose of a study are allowable under this policy.
- C. No modifications to the Principal Investigator are allowable under this policy.

# 4. Special Instructions

- A. The IACUC Committee via the Chair must officially delegate this authority in writing to individuals with the experience appropriate to make determinations.
- B. Individuals with a conflict of interest on a protocol may not be designated as administrative or veterinary reviewers.

## 5. References

- A. Guide for the Care and Use of Laboratory Animals.
- B. Office for Animal Laboratory Welfare (OLAW) Notice NOT-OD-14-126, *Guidance on Significant Changes to Animal Activities*<sup>2</sup>, August 2014