

Title: Continuing Review, IACUC Administrative Policy # P-0025-01

Approval Date: March 15, 2018

Authorized by: Institutional Animal Care & Use Committee

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I. PURPOSE

Federal regulations and policies mandate that institutions develop review procedures that are reasonable, meaningful and efficient; such procedures should contribute directly to the welfare of the animals and/or provide significant information relevant to the role of the IACUCs.

The PHS Policy at IV.C.5. states "the IACUC shall conduct continuing review of activities covered by this policy at appropriate intervals as determined by the IACUC but not less than once every three years" while the USDA Animal Welfare Act & Regulations (CFR2.31 (d) (5)) states that the IACUC "conduct continuing reviews of activities...at appropriate intervals as determined by the IACUC, but not less than annually".

The purpose of continuing review is threefold:

- To inform the IACUC of the current status of the project
- To ensure continued compliance with PHS, USDA and institutional requirements
- To provide for re-evaluation of the animal activities at appropriate intervals

The use of continuing review is also a mechanism used to support the university's post-approval monitoring (PAM) program.

II. POLICY

Continuing review of each approved animal use protocol must be completed by each of the (typically) three anniversaries of the protocol's initial approval. For the first two years of a project, approval lapses if continuing review has not been completed by the protocol's approval anniversary. In such a scenario, all work using animals covered by the lapsed protocol must cease.

Note: Some funding agencies (e.g. PHS) require notification when approval lapses for protocols covering funded projects.

III. PROCEDURE

- A. Approximately three months before the anniversary of a protocol's original approval date, Principal Investigators (PIs) will be alerted that the anniversary of their protocol's approval is approaching and will be sent instructions regarding how to complete the continuing review process in IRBManager.
 - 1. Information requested on the form in IRBManager includes:
 - a. PI name
 - b. Protocol Identification (Number and Title)
 - 2. Current project status. Either:
 - a. Project is active and continuing
 - b. Project has been completed
 - 3. Species/strain of animals and numbers of each used in past 12 months
 - 4. Unexpected Adverse Events – as defined in IACUC policy P-0019-01* – of the past 12 months
 - 5. A list of all personnel currently approved to work on the project

- B. If necessary, PIs will receive reminder emails at approximately two months, one month and one week before the protocol's anniversary date.
- C. Reviews, Approval, Requests For Additional Information
 - 1. The IACUC Administrator, the Chair, the Co-Chair, or one of the AVs may approve continuing reviews if:
 - a. No Unexpected Adverse Events as defined by policy P-0019-01 are reported
 - b. Reported animal usage remains within the number of animals approved for use in the PI's protocol
 - 2. Continuing reviews that include reports of Unexpected Adverse Events as defined by policy P-0019-01 will be provided to the committee for review and will be reviewed following the order of events used for review of protocols and amendments.
 - a. The continuing review will be provided for a period of open comment by the committee
 - b. During the open comment period, any member may call for full committee review (FCR) at the next convened IACUC meeting.
 - c. If no member calls for FCR, the Chair, or the Chair's designee will designate reviewers to evaluate the continuing review.
 - d. The designated reviewers may:
 - i. Approve the continuing review
 - ii. Request FCR
 - iii. The periods for each step will match those allotted in the review process for protocol and amendment review

* Per the Reporting Unexpected Adverse Events - IACUC Administrative Policy P - 0019 – 01:

An unexpected adverse event is an occurrence of an unforeseen event that negatively affects the welfare of research animal(s); that is, an event that involves pain, distress, and/or death of the animal. By definition, these are events that are not identified as a possible risk or outcome in the IACUC approved protocol.