

TITLE: Institutional Animal Care and Use Committee Policy on Protocol Renewals: Annual & Third Year (Expiration)

PURPOSE: Protocols are approved for three years by the Institutional Animal Care and Use Committee (IACUC) based on Public Health Service (PHS) Policy guidelines. Annual renewal and review of approved protocols is required by the United States Department of Agriculture (USDA) Animal Welfare Act. This Policy outlines the procedures for both types of renewals: Annual and Third Year.

REVIEW/REVISIONS: Permanent amendment/revisions to this policy must be presented to the IACUC for review before implementation and should be developed by the Office of Animal Welfare Assurance (OAWA) Staff and/or IACUC membership.

EFFECTIVE DATE: 11/06/2008

PERSON(S) RESPONSIBLE: Principal Investigators, IACUC Membership and Staff

POLICY/PROCEDURES:

Annual Renewal

1. Two Annual Status Reports must be completed during the three year approval period for each protocol. The reports must be received by the OAWA prior to the start of the second and third years of the protocol.
2. *Approximately **Two Months*** before the protocol anniversary date an email will be sent to the Principal Investigator (PI) and protocol contact (if known) with an attachment containing a partially completed Annual Status Report for the renewing protocol.
 - a. The Annual Status Report and email will contain a due date for receipt of the Annual Status Report back from the PI.
3. *Approximately one week* prior to the Annual Status Report due date, if the Annual Status Report **has not** been received by the OAWA Office, a follow up email will be sent to the PI and protocol contact reminding them of the upcoming due date.
4. *On the first business day* after the annual status report due date, all protocols **lacking** an Annual Status Report will be placed in an 'On-Hold' status. The PI and protocol contact will be notified via email that the protocol has been placed on hold due to the lack of a current annual status report.
 - a. The PI will be unable to order animals for any protocol in an 'On-Hold' status.
 - b. The protocol will be restored to an 'Approved' state with the completion of the Annual Status Report.
5. Returned Annual Status Reports are processed by a designee of OAWA manager in the following manner prior to review at an IACUC committee meeting:
 - a. Participating Personnel – updates to the active protocol personnel list are made according to IACUC policies concerning protocol participation
 - b. Review of PI comments in sections concerning *Unexpected Clinical Signs* and *Changes to Protocol Not Addressed by an Amendment* – Annual Status Reports with either unexpected clinical signs or non-approved changes are flagged for additional review at an IACUC committee meeting



- c. The *Past Years Progress Description* and *Next Year's Activities Planned* sections are compared to the full protocol. Annual Status Reports with progress descriptions that do not match the protocol document are flagged for additional review at an IACUC committee meeting
6. Annual Status Reports are reviewed at an IACUC committee meeting after the OAWA staff review and prior to the annual renewal due date for the protocols to be reviewed.
 - a. Action is taken as decided by the IACUC committee during review
7. Protocols with a current (approved) Annual Status Report continue with no interruption.

Third Year Renewal

1. *Approximately Four Months* before the protocol expiration date an email will be sent to the Principal Investigator (PI) and protocol contact (if known) with an attachment containing a memo concerning the upcoming protocol expiration.
2. *Approximately One Month* before the protocol expiration date, PIs will be contacted by the OAWA office concerning animals in the animal facility on expiring protocols lacking a renewal protocol. The consequences of having animals in the facility at the time of expiration, as outlined below, will be included in the email. University Animal Care staff will receive a copy of the email.
3. On the ***day after the protocol's expiration date*** no further experimental manipulation under this protocol will be permitted. **If animals remain in the facility, and a renewal protocol has not been approved, the OAWA Office will do the following:**
 - a. Notify University Animal Care and the PI that the investigator and all staff listed on the protocol are denied access to the animal facility. A reference list of all protocols the affected staff participates on will be provided as well. *Please Note:* Animal facility access will be revoked even if the personnel affected are listed on other currently approved protocols for the same PI.
 - b. Notify the Institutional Official and PI's department head that the protocol has been officially suspended by the IACUC.
 - c. If the PI is currently **breeding animals** on the expired protocol, an email will be sent to the PI and University Animal Care authorizing the separation of all breeding pairs at the PIs expense.
4. Upon approval of a *renewal protocol* for a protocol that has been allowed to expire where animals are housed in a University Animal Care facility:
 - a. University Animal Care will be notified by the OAWA staff that the renewal protocol has been approved. At this point facility access can be restored and breeding animals re-mated at the PIs expense.
 - b. It is the PI's responsibility to provide the granting agency with proof that the renewal protocol has been approved by the IACUC Committee.

FEDERAL POLICY:

Public Health Service Policy

The Public Health Service Policy states that animal protocol approvals may not be granted for more than 3 years, and extensions may not be approved administratively. Conducting animal activities – including housing, breeding, interventions/ experimental manipulations, and euthanasia – after a protocol has expired is a violation of NIH grants Policy, as well as the PHS Policy. The Office of Laboratory Animal Welfare (OLAW) views such activity as a serious violation of the PHS Policy and these instances must be promptly reported to OLAW by the University’s Institutional Official. Institutions are also required to report to the appropriate NIH Institute/center any charges to grant awards for the conduct of animal activities during lapses or after expiration of IACUC approval.

USDA Animal Welfare Act

The USDA also requires continuing review of animal use protocols by the institution’s committee for the care and use of animals. The USDA stipulates that these renewals must be done no less than annually.

Upon suspension of the protocol, Section 2.31 (d)(7) requires notification to the USDA Animal and Plant Health Inspection Service (APHIS) and any federal agency funding the grant.

JUSTIFICATION:

The **National Institutes of Health (NIH)**(*Public Health Service Policy on Humane Care and Use of Laboratory Animals*; Health Research Extension Act of 1985, Public Law 99-158) and **United States Department of Agriculture (USDA)**(*Animal Welfare Act: Title 9, Part 2, Subpart C*) provide operating standards for Institutional Animal Care and Use Committees, including requirements for continuing review of animal research protocols.

The University of Arizona is registered as an animal research facility with NIH and USDA. In addition, the University of Arizona is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).