

**University of Cincinnati
Animal Care and Use Program**

Document Submission

The UC Animal Care and Use Program (ACUP) recognizes the need for an efficient and timely mechanism of federally mandated annual and triennial continuing reviews.

Annual Continuing Reviews:

Federally Mandated Continuing Reviews- The USDA (AWAR, 2.31,d.5), DOD (DOD 3216.01) and VA (VHA Handbook 1200.07) mandate annual continuing reviews of protocols.

Note: VA and DOD require annual reports directly to the VA/DOD. As an affiliate, UC does not process these VA and DOD annual reviews.

The Animal Welfare Act Regulations specify that “The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually” (9 CFR 2.31(c)(5)). In the past, this has been interpreted as requiring no more than 365 days between reviews.

Recent guidance from USDA APHIS has clarified that continuing reviews are considered compliant if they are completed within the anniversary month of the most recent previous approval or completion of a continuing review (Animal Welfare Inspection Guide, 7.4.1.6). Even if the continuing review process begins in the preceding month, as long as it is completed (reviewed and approved) within the anniversary month, the anniversary date will remain unchanged.

1. Annual continuing reviews for the first and second anniversary of a protocol must be submitted by the PI prior to anniversary date.
2. IACUC will review the annual report, and annual review will have an approval effective on the anniversary date.
3. Triennial reviews are also considered annual continuing reviews, and do not require an additional annual report submission; as long as the previous annual continuing review was approved within the protocol approval anniversary month.
4. Annual reviews submitted after the last day of the anniversary month will be considered non-compliant, and once approved the anniversary date will move to the new month of approval.

Triennial Reviews:

The PHS Policy (IV,C 5) requires a complete review of protocols at least every three years. The PI is required to submit an updated protocol for continuing activities prior to the three year expiration of their protocol if they wish to continue work.

1. To avoid protocols expiring with animals in-house, the IACUC strongly recommends the triennial submission of protocol updates 3 months prior to the expiration of the protocol.
2. A properly completed protocol application (including all appropriate safety applications/approvals) requires approximately 30-45 days for processing depending on the complexity of the project.
3. Note: It is the PI's responsibility to ensure that a completed new/triennial submission is submitted in enough time to be reviewed and approved prior to the expiration date.

If the protocol expires:

1. A protocol closure notification will be sent to the PI and LAMS.
2. No research can be conducted on an expired protocol (including but not limited to: breeding, euthanasia and tissue harvest).
3. Any animals assigned to the protocol will be transferred to a LAMS holding protocol at the PIs expense. Once animals are transferred to the holding protocol, the veterinarian will decide the disposition of confiscated animals.
4. Many granting agencies do not allow sponsored monies to be used pay per diems while on the holding protocol. PIs will need to check with their grant administrator to identify whether alternate funds are needed to support per diems on these animals.