Document Submission

The UC IACUC 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. 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. Following is an example with specific dates:

- March 1, 2014: A protocol is approved by the IACUC
- February 28, 2015: If the continuing review is completed on this date, it is compliant with USDA/VA/DOD requirements, but the anniversary date for the next continuing review becomes February 28, 2016.
- March 1-31, 2015: If the continuing review is completed anytime in March of 2015 (even if the IACUC began the review in February), it is compliant with USDA/VA/DOD requirements, and the anniversary date for the next review will remain March 1, 2015.
- April 1, 2015: If the continuing review is completed on this date (after March 31, 2015), it will be non-compliant with USDA/VA/DOD requirements, and the anniversary date for the next review will become April 1, 2016.

Annual continuing reviews for the first and second anniversary of a protocol must be submitted by the PI prior to anniversary date.

IACUC will review the annual report, and annual review will have an approval effective on the anniversary date.

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.
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. 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. This ensures that sufficient time is available for both the preliminary review and the IACUC review. It does NOT guarantee approval as changes or additions may be required.