TITLE: Protocol Annual Renewal (USDA Regulated Species) and Continuing Reviews

PURPOSE: Annual review and renewal of approved protocols is required by the United States Department of Agriculture (USDA) Animal Welfare Act. Furthermore, the IACUC requires a Continuing Review for all protocols, regardless of species. This SOP outlines the procedures for completing a Continuing Review.

DATE OF LAST REVISION: 08/17/2016

The USDA requires continuing review of animal use protocols by the IACUC. The USDA stipulates that these renewals must be done no less than annually. The Continuing Review serves as the mechanism by which the IACUC performs annual review of protocols with USDA regulated species that have a three year approval.

For all species, the Continuing Review also serves as a mechanism for post-approval monitoring of IACUC protocols.

PROCEDURE:

1. Continuing Reviews must be completed during the three year approval period for each protocol. The reports must be received by the IACUC Office prior to the start of the second and third years of the protocol.

2. Approximately 45, 30 and 15 days before the protocol anniversary date, an eSirius 3G system-generated reminder email is sent to the Principal Investigator. Note that the eSirius system DOES NOT send the Continuing Review reminder emails to anyone other than the PI.

3. Approximately 1-2 weeks prior to the due date, if a completed Continuing Review has not been received, the IACUC Office sends a reminder email to the PI, co-PI and protocol contacts.

4. Continuing Review are processed by the IACUC Office in the following manner:

   a. The IACUC is notified of submission of the Continuing Review. The IACUC may call for Full Committee Review (FCR) of the Continuing Review.
   b. In the absence of a call for FCR, the Continuing Review is reviewed by a Designated Member Reviewer (DMR) assigned by the IACUC Chair. The DMR is responsible for reviewing and approving the Continuing Review and supporting documents, such as wildlife permits, if any, to ensure compliance with the approved protocol.
      i. If the DMR cannot approve the Continuing Review with or without modification, it is referred to FCR for review.
   c. If identified by the DMR, the IACUC is notified of any non-compliance and/or adverse events/unanticipated outcomes via the appropriate procedures.

5. Protocols with an approved Continuing Review continue with no interruption.

For non-USDA-regulated species:

Continuing reviews for non-USDA-regulated species are not required under the AWA or PHS Policy. However, the IACUC requires them at approximately yearly intervals as a way of encouraging protocol review and modification, as well as post-approval monitoring.
1. If a Continuing Review is not submitted by the due date, Sirius 3G prevents the ordering of new animals and printing of new breeding packets or cage cards.

2. The IACUC may be notified of the lack of Continuing Review submission, depending on the specific circumstances. In this case, the IACUC determines the appropriate actions to be taken, including notifying the Institutional Official and reporting to OLAW, as appropriate.

3. Once a Continuing Review is submitted, reviewed and approved, ordering/cage card restrictions are lifted.

For USDA-regulated species:

Ideally, Continuing Reviews should be submitted at least one week prior to the due date to allow review and approval within the required timeframe. The USDA has provided guidance that review and approval within the same month is allowed, as long as extending the deadline does not artificially extend the annual review period over time.

1. If a Continuing Review is not submitted by the due date, the action depends on the specific circumstance.

   a. If no animals are on the protocol, the protocol is closed.
   b. If animals are on the protocol, they are moved to the holding protocol the first business day after the due date. Animals remain on the holding protocol for up to 14 days past the due date. The PI is notified of the exact number of days by the IACUC Office. The exact number of days depends on the proximity of the due date to the end of that month.

2. For protocols with animals placed on the holding protocol:

   a. If the Continuing Review is submitted, reviewed and approved within the date provided by the IACUC Office, the animals are transferred back to the protocol. The anniversary (approval) date remains unchanged.
   b. If the Continuing Review is not submitted, reviewed and approved within the date provided by the IACUC Office, the protocol is closed and the disposition of the animals on the holding protocol is as follows:

      i. Non-naïve animals, i.e., that have been treated with compounds and/or invasive procedures, are euthanized.
      ii. Naïve animals may be euthanized, may remain on the holding protocol or may be transferred to an appropriate protocol.

3. The IACUC is notified of the lack of Continuing Review submission, depending on the specific circumstances. In this case, the IACUC determines the appropriate actions to be taken, including notifying the Institutional Official and reporting to the USDA and OLAW, as appropriate.