Institutional Animal Care and Use Committee

Standard Operating Procedure

Continuing Review of Animal Research

Regulatory Requirements

The Public Health Service (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 (3)“.

The USDA regulations 9 CFR 2.31(a) (5) use similar language, except that continuing review must be performed not less than annually. The Animal Welfare Act (AWA) requires that, whenever possible, researchers should Replace, Reduce, and Refine (the three R’s) animal use. This means:

- Replacing animals in part or full with non-animal systems (e.g., in vitro, computer or mathematical models) or less sentient animal species (e.g., insect or molluscan models instead of mammalian models).
- Reducing the number of animals to the minimum required to obtain scientifically valid data through a priori consideration of appropriate experimental and statistical design (e.g., more advanced statistical tests, power analyses).
- Refining procedures to lessen or eliminate pain or distress, thereby enhancing animal well-being (e.g., less-invasive surgical techniques, terminating experiments during earlier rather than later stages of morbidity).

Investigators on all categories of protocols are encouraged to conduct regular searches of appropriate journals and databases for new methods that would support these goals. Such a search is required on an annual basis for all Category D and E protocols. Any techniques or approaches that could reduce animal use or animal pain or distress without adversely affecting experimental outcomes should be incorporated into a protocol.

Oakland University’s PHS Policy Assurance states that the IACUC, “conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review...at least once every three years. The IACUC procedures for conducting continuing reviews are as follows: Principal Investigators, who have a current IACUC Project Approval Period greater than one year, but less than three years, are required to submit a properly completed, “Annual Review of Approved Projects Form” to the IACUC within 30 days of the yearly anniversary date(s) of their original IACUC approval. All ongoing projects receive a complete and new review by the IACUC every three years.”

Policy

At Oakland University, regardless of the species used, the IACUC requires an annual review on the status of each protocol. When the Annual Review of Approved Projects Forms are submitted to the IACUC prior to the protocol’s expiration date, the protocol is considered active and experiments can be conducted while the forms are under review.
The Annual Review of Approved Projects forms are subject to the same IACUC review outcomes as the original protocol. These outcomes are:

- Approve
- Requires modifications to secure approval
- Withhold Approval

Annual Review of Approved Projects Forms are reviewed for completeness and to assure that the number of animals used has not exceeded the number approved; and that the personnel listed on the protocol have completed all CITI Program training requirements. Please note that Annual Review of Approved Projects forms of IACUC approved protocols will not be approved if CITI Program training has expired and the refresher course has not been successfully completed by all research personnel listed in the protocol.

If the Annual Review of Approved Projects Forms are not submitted before the yearly anniversary date(s) of their original approval, the Principal Investigator will be restricted by not being able to submit a request for a revision to the protocol, and will not be able to purchase or procure any additional animals for use in the project, until the forms are submitted.