



Institutional Animal Care and Use Committee

Standard Operating Procedure

Continuing Review of Animal Research

Regulatory Requirements

In accordance with PHS policy at IV.C.5, the Oakland University IACUC will conduct continuing review of each previously approved project at appropriate intervals as determined by the IACUC, but not less than once every three (3) years. The triennial review will include a complete “de novo” review of research, teaching, and testing in accordance with PHS Policy.

In accordance with USDA requirements at 9 CFR 2.31(a), the OU IACUC will conduct review of ongoing research, teaching, and testing at least annually regardless of species.

Purpose of Continuing Review

The USDA has interpreted the role and purpose of the annual review as a form of monitoring the use of animals. The purpose of the annual review is to provide the IACUC with an update on the current status of the protocol, an update in the number of animals used in the previous year, progress on the protocol, as well as whether there have been any adverse events, and if there have been or will be any modifications to the IACUC approved protocol. In addition, the Animal Welfare Act (AWA) regulations require that, whenever possible, research should replace, reduce, and refine animal use. Toward this end, researchers are also required to complete a literature search to determine if alternatives to animal models or painful or distressful procedures have been identified since the protocol has been approved.

Compliance with the PHS Policy regarding triennial review has been interpreted to mean that the IACUC will conduct a complete and “de novo” review of the project. To meet the requirements of a “de novo” review, the IACUC must ensure that the protocol meets the regulatory criteria at IV.C.1.a-g of the PHS policy which addresses factors such as pain and distress, pain relief, animal husbandry, veterinary care, personnel qualifications and methods of euthanasia as well as compliance with the “Guide for the Care and Use of Laboratory Animals.”

Annual Review Procedures

The IACUC procedures for conducting annual 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. Annual reports are required for all investigators with a current approved protocol regardless of the species.

As noted above, 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).

Principal Investigators are encouraged to conduct literature searches to address the above three goals. Such a search is required on an annual basis for protocols classifying animals in pain categories D or E. 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.

IACUC Annual Review

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.

Annual Review of Approved Projects forms are reviewed by the fully convened IACUC on a monthly basis. The forms are reviewed for completeness to assure that the number of animals used has not exceeded the number approved and that the personnel listed on the protocol are current with the OU IACUC CITI training requirements. The IACUC further evaluates the adequacy of the literature search to ensure that no alternative animal models or procedures involving pain or distress have been identified.

The Annual Review of previously Approved Projects forms are subject to the same IACUC review outcomes as the original protocol. These outcomes include:

- Approve
- Requires modifications to secure approval
- Withhold Approval

Annual reviews will not be approved if deficiencies in the annual review form are identified. Annual reviews that "requires modifications" must be reviewed by the fully convened IACUC after revisions have been made. In addition, **annual reviews of IACUC approved protocols will not be approved if CITI training has expired and the refresher course has not been successfully completed.**

In general, IACUC-approved research activities will not be halted if the Annual Review Form is not approved prior to the yearly anniversary date. **However, please note that if this situation arises the Principal Investigator will be restricted in the following manner until annual approval is secured:**

- **The IACUC will not review a request for revision to the protocol**
- **The investigator will be prohibited from purchasing or procuring any additional animals for use on the project**

Triennial Review Procedures

In accordance with PHS policy, the OU IACUC approves protocols for research, teaching, and testing for a period of three (3) years. Per PHS policy, IACUC approval may not exceed the

three year approval period by any means other than a “de novo” review and approval. After 3 years, investigators are required to submit an entirely new animal research application. Investigators will be notified at least 1 month prior to expiration of the protocol to submit a new application if the research, teaching and testing will be continuing. The IACUC will review the protocol in accordance with guidelines for new protocol review. If the protocol expires, ALL research, teaching and testing activity on the protocol must stop without exception. Continuation of research activity beyond the expiration of the study will result in noncompliance reportable to federal agencies.