Animal Research Protection Program
Policies & Procedures

Lapsed or Suspended Approval: Disposition of Animals in an IACUC

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Research Integrity Office
Mail code L106-RI
Portland, Oregon 97239-3098
Phone: 503-494-7887
Fax: 503-494-5081

I. BACKGROUND

A. The IACUC must conduct continuing reviews of previously approved, ongoing animal research and education protocols at appropriate intervals as required by federal regulations and the IACUC.

B. The period of approval for any protocol (research or education) involving the use of animals at OHSU is stated in the approval memo to the investigator and is based upon the species of animal being used (USDA-regulated or non-USDA-regulated) and the procedures being done with the animal.

C. A lapse in IACUC approval will result in restriction of research activities and/or expenditures by the granting agency. Because these restrictions will delay research and add to departmental expenses for maintaining research animals, the IACUC provides multiple notifications to the PI in advance of the expiration date.

II. SCOPE

A. The purpose of this policy is to describe what may and may not be done with animals assigned to research or education protocols when IACUC approval has lapsed.

B. This policy applies to the Central/Waterfront Campus and the West Campus.

III. POLICY

A. All animals used and maintained by OHSU must be included in an active, IACUC-approved protocol.

B. When approval for an animal protocol has lapsed or been suspended:

1. The investigator must discontinue all protocol-dictated use and activity (i.e., all research or teaching) related to the animals.
2. Disposition of the animals will be decided by the IACUC in consultation with the Department of Comparative Medicine (DCM) or the Department of Animal Resources (DAR) and the PI.
3. The animals may be transferred to the care of DCM or DAR for husbandry until their disposition is determined.
4. Charges for animal husbandry must be moved to non-federal department funds.
5. Because PHS funding agencies may allow these maintenance and care costs to be charged to grants on a case-by-case basis, the investigator must obtain permission from the Institute/Center supporting the award if he/she wishes to charge the grant during the period of lapse.
6. If a grant is charged during a period of lapsed approval without funding agency authorization, OHSU is required to report those charges to OLAW and the funding agency.

IV. PROCEDURES

A. The IACUC will send notifications to investigators in advance of the lapse date. The notifications will contain a “due by” date that allows time for pre-review and scheduling for committee review. The notification will remind investigators that all research or teaching-related animal activity must stop if the protocol is allowed to lapse.

B. If a renewal application is not received by the “due by” date, the investigator and a department/unit administrator will be notified that the approval is in danger of lapsing and that, upon lapse, all charges associated with the protocol must be moved to a non-federal grant department fund.

C. If an application for renewal has not been received and approved by the lapse date, the IACUC will notify the investigator and the department/unit administrator that approval has lapsed and all research or teaching activity with the animals must stop.

D. The IACUC will notify the Department of Comparative Medicine or Division of Animal Resources of the lapse/suspension to ensure that charges are moved to an appropriate account.

E. The IACUC will notify Sponsored Projects Administration to ensure that no further charges associated with the protocol are made to the grant or grants supporting it. The IACUC and/or Sponsored Projects Administration will assist the investigator in contacting the program official at the appropriate funding agency if permission to charge the grant for animal husbandry costs is desired.

F. Absent authorization from the funding agency to charge husbandry costs to a grant during a period of lapsed approval, investigators must do the following:

1. If DCM or DAR agrees, the animals may be moved to a holding protocol. In this case, DCM or DAR will provide husbandry services (housing, food, water, dividing cages, and standard veterinary care) but cannot provide any protocol-dictated procedures (breeding, genotyping, etc.). DCM or DAR will charge a non-federal department fund indicated by the investigator for the husbandry services on a per diem, per cage basis.

2. The investigator or study staff may provide medications or other care as needed for the survival of the animals but not for experimental purposes. No data may be collected during the period.

3.

G. The IACUC will work with the PI and department to resolve the lapsed approval in an expeditious manner.

V. DEFINITIONS

A. Animal Husbandry: Routine housing, feeding, watering, and care-taking procedures to ensure the well-being of animals.

B. Continuing Review: Periodic IACUC review by full committee or designated member review (as appropriate and permitted by regulation) of previously approved protocols.

C. Lapse: Failure to submit a protocol for continuing approval at specified periods. A lapse in approval will generally occur at annual intervals if application for continuing review has not been submitted.

D. Suspension: A determination by the IACUC to suspend approval for all animal-related activity associated with a protocol. Suspensions must be reported to the funding agency and to the Office for Laboratory Animal Welfare.

VI. AUTHORITY

A. PHS IV(C)5: “Review of PHS-Conducted or Supported Research Projects.” The IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance

with IV.C.1.-4. at least once every three years.
http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples

B. AWA 9 CFR 2.31(d)(5): "Institutional Animal Care and Use Committee (IACUC)." 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.
http://edocket.access.gpo.gov/cfr_2008/janqtr/pdf/9cfr2.31.pdf

C. OLAW: NOT-OD-10-081: "Guidance on Confirming Appropriate Charges to NIH Awards during Periods of Noncompliance for Activities Involving Animals." The Office of Management and Budget Cost Principles…do not permit charges to grant awards for the conduct of live vertebrate animal activities during periods of time [when there is] failure to obtain IACUC approval, expiration, or suspension of IACUC approval. http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-081.html

D. PHS IV.B.8: "Functions of the Institutional Animal Care and Use Committee." As an agent of the institution, the IACUC shall with respect to PHS-conducted or supported activities… be authorized to suspend an activity involving animals in accordance with the specifications set forth in IV.C.6 of this Policy. http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples

E. PHS IV(F)3: "Reporting Requirements." The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing noncompliance with this Policy;
2. Any serious deviation from the provisions of the Guide;13 or
3. Any suspension of an activity by the IACUC.
http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples

VII. GUIDANCE

A. NIH FAQS

How frequently should the IACUC review research protocols?

Under PHS Policy the maximum interval between IACUC review and approval is three years, i.e., a complete *de novo* review is required at least every three years. The review must encompass all of the criteria in the Policy at IV.C.1.a.-g. See references at A2 and A6 for detailed guidance in how to satisfy this Policy requirement and the USDA requirement for annual review.
http://grants.nih.gov/grants/olaw/faqs.htm#d1

May the IACUC administratively extend approval of a project that has expired?

No. IACUCs do not have authority to administratively extend approval beyond three years. When IACUC approval expires the protocol lacks valid approval. Continuation of animal activities in the absence of valid approval is a serious and reportable violation of PHS Policy (see NOT-OD-05-034).
http://grants.nih.gov/grants/olaw/faqs.htm#d1