

IACUC Policy: Managing Exemptions from Standards of Care

The intent of this policy is to clarify the types of exemptions from standards of animal care, and the procedure for requesting and reporting such exemptions.

1) Policy

- A. Care and use of animals in research, teaching or testing must adhere to federal regulations (Animal Welfare Act, AWA) and University policies and guidelines. Deviations from the standards of care outlined in the Animal Welfare Regulations (AWR), *Guide for the Care and Use of Laboratory Animals (the Guide)*, IACUC approved Animal Care and Use Procedures or IACUC policies must be reviewed and approved by the IACUC. Approved deviations from standards of care are referred to as exemptions.
- B. The IACUC may grant standing exemptions for certain procedures. Such exemptions do not require that a separate exemption be filed by the PI nor do they need to be described in the protocol, except as relevant to the protocol.
- C. Deviations from regulatory standards, which are detailed in the following sections in the IACUC protocol, do not require a separate exemption form. Such deviations are reviewed on an annual basis as part of the annual review of the protocol.
 - 1 Housing Outside Approved Facility
 - 2 Transportation of Animals
 - 3 Enrichment and/or Exercise
 - 4 Clinical Care, Quarantine, Acclimatization and Daily Care
 - 5 Euthanasia Methods

Deviations from the *Guide* are reviewed semi-annually and reported to in the IACUC semi-annual report to the Institutional Official (IO).

- D. The Attending Veterinarian (AV) or designee may exempt an animal from standards of care based on its health, condition or in consideration of its well-being. Such exemption must be documented by the AV or designee and must be reviewed at least every 30 days by the AV or designee, unless the basis for exemption is a permanent condition.
- E. The Principal Investigator (PI) may request an exemption from standards of care based on scientific justification.
- F. When deviations from standard husbandry practices (e.g. sanitization of objects/housing, size of primary or secondary enclosures, materials used for housing or enrichment) are proposed, the PI must request an exemption and the IACUC must review and approve the exemption every six months.

2) Procedure

- A. If the PI is requesting an exemption from the *Guide* or the AWRs:
1. The request for exemption must be described in the IACUC application.
 2. The request for an exemption will be reviewed by the IACUC and must be approved prior to instituting the deviation from standards.
 3. Once approved, a copy of the exemption from the approved protocol must be readily available where the covered animals are housed.
 4. The exemption will be reviewed either annually or every 6 months.
- B. If the exemption is no longer needed, the PI must file an amendment to remove the exemption.
- C. If any revisions are made to an approved exemption, the PI must file an amendment, and the amendment must be approved by the IACUC prior to instituting the change.
- D. Exemptions involving USDA species are included in summary form on the annual report to USDA.

3) Regulatory Mandates and Guidelines

A. USDA AWR 9 CFR Part 2 Subpart C

- 1 2.31(d)... The IACUC shall determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing...
- 2 2.31(d)(1)(xi)..Methods of euthanasia must be in accordance with the definition of the term set forth in 9 CFR ...unless a deviation is justified for scientific reasons, in writing, by the investigator

B. PHS Policy on the Humane Care and Use of Laboratory Animals

- 1 C.1...the IACUC shall confirm that the research project will be conducted in accordance with the AWA insofar as it applies to the research project, and the research project is consistent with the Guide unless acceptable justification for a departure is presented.
- 2 Guideline
 - *Guide for the Care and Use of Laboratory Animals* (8th ed., Committee for the Update of the Guide for the Care and Use of Laboratory Animals, Institute for Laboratory Animal Research (ILAR); National Research Council, Washington, DC, 2011) [The Guide]