IACUC GUIDELINE: Managing Exemptions from Standards of Care

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<th>SOP #</th>
<th>IACUC Approval:</th>
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**Purpose:**
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.

**Scope:**
The requirements specified in this policy for managing exemptions from standards of care apply to all vertebrate animal species used in Institutional facilities, under the jurisdiction of the Texas A&M University Commerce IACUC.

**Policy:**
A. Care and use of animals in research, teaching or testing must adhere to federal regulations and University policies and guidelines. Deviations from the standards of care outlined in the Animal Welfare Act Regulations (AWR), Guide for the Care and Use of Laboratory Animals (the Guide), Guide for the Care and Use of Agricultural Animals in Research and Teaching (the Ag Guide), IACUC approved Animal Care and Use Procedures (SOPs) or IACUC policies must be reviewed and approved by the IACUC. Approved deviations from standards of care are referred to as exemptions.

B. Deviations from regulatory standards or IACUC approved Animal Care and Use Procedures (SOPs) and Policies are detailed in the IACUC protocol. Deviations from the Guide or AWR are reviewed semi-annually and reported in the IACUC semi-annual report to the Institutional Official(IO).

C. The Attending Veterinarian or designee may exempt an animal from standards of care for veterinary or animal welfare reasons. This exemption must be documented by the Attending Veterinarian or designee and must be reviewed at least every 30 days by the Attending Veterinarian or designee, unless the basis for exemption is a permanent condition.

D. The Principal Investigator (PI) may request an exemption from standards of care based on scientific justification.

**Procedure:**

A. If the PI requests an exemption from the Guide or the Animal Welfare Regulations (AWRs):
   1. The exemption must be described in the AUP.
   2. The exemption will be reviewed semi-annually by the IACUC and reported to the IO as part of the semi-annual report.
   3. Once approved, a copy of the exemption from the approved protocol must be readily available where animals covered by the exemption are housed.
   4. Animal usage on exemptions involving USDA regulated species will be included in the annual report to the USDA.
   5. Examples:
      - Dogs are housed singly to allow for fecal collection from individual animals. This is a deviation from the Guide which states “Social animals should be housed in stable pairs or groups of compatible individuals unless they must be housed alone for behavioral reason or because of social incompatibility.” (p51)
      - Pigs are housed for 48 hours in metabolism cages to collect urine. This is a deviation from the Guide specification of 8 ft 2 per <15 kg pig (p62).
B. Deviations from SOPs, Animal Bio-Safety Procedures (ABPs) and IACUC policies, are also considered exemptions. Such deviations must be described in the animal use protocol but are not reportable to the IO or USDA.

C. All exemptions must be approved by the IACUC prior to implementation.

D. If an exemption is no longer needed, the PI should contact the IACUC office.

E. If the PI wishes to make a change to an approved exemption, s/he must file a protocol amendment, and the amendment must be approved by the IACUC prior to instituting the change.

**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

3. 3.8(d)... A research facility may be exempted from the requirements of this section *exercise for dogs* if the PI determines for scientific reasons that ...that it is inappropriate for certain dogs to exercise. Such exemption must be documented in the proposal and must be reviewed at appropriate intervals as determined by the Committee, but not less than annually.

**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.

**C. Guidelines**

1. Guide for the Care and Use of Laboratory Animals (ILAR, 2011) [the Guide]
2. Guide for the Care and Use of Agricultural Animals in Research and Teaching, 3rd edition (FASS, Jan 2010) [the Ag Guide]

**History:**

Version 01 – Petra Collyer, Venugopalan Cheriyath
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