

**THE UNIVERSITY OF HOUSTON
IACUC POLICY AND GUIDANCE**

Title: Exemptions from Standards of Care for USDA-covered species

Background:

The Animal Welfare Act and Animal Welfare Regulations (**AWAR**); U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training (**the “Principles”**); the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (**the “PHS Policy”**); and the Office of Laboratory Animal Welfare Frequently Asked Questions (**OLAW FAQs**) all provide guidance clarifying types of exemptions from standards of animal care, and procedures for requesting and reporting such exemptions:

<p>AWAR 9CFR, Part 3, Subpart A, §3.8 (d) (1), (2), and (3); 9CFR, Part 3, Subpart D, §3.81 (e) (1), (2), and (3)</p>	<p>U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training</p>	<p>PHS Policy (IV.C.1) OLAW FAQ #14</p>
<ul style="list-style-type: none"> The attending veterinarian (AV) may determine that an animal should be exempted from meeting species-related requirements for enrichment, housing, and/or husbandry. Such exemptions must be documented by the AV and reviewed at least every 30 days by the AV. The IACUC may determine that an animal may be exempted from such requirements based on scientific reasons set forth by the principal investigator (PI) in an approved research proposal. Such exemptions must be reviewed at appropriate intervals as determined by the Committee, but not less than annually. 	<p>II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.</p> <p>IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group, such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.</p>	<ul style="list-style-type: none"> PHS Policy: [T]he IACUC shall confirm that the research project will be conducted in accordance with the Animal Welfare Act insofar as it applies to the research project, and that the research project is consistent with the <i>Guide [for the Care and Use of Laboratory Animals]</i> unless acceptable justification for a departure is presented. OLAW FAQ: Exemptions ... must be based on strong scientific justification approved by the IACUC or for a specific veterinary or behavioral reason. Lack of appropriate caging does not constitute an acceptable justification for exemption.

Scope:

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

Policy:

An **exemption** occurs when deviating from regulatory standards for the care and use of vertebrate animals in testing, research, and educational activities. A request for an exemption, with appropriate justification/documentation, must be submitted to the Institutional Animal Care and Use Committee (IACUC) for review and approval.

- The Attending Veterinarian (AV) may exempt an animal from standard care based on its health or condition or in consideration of its well-being. The basis of the exemption must be recorded by the AV and reviewed at least every 30 days. It is required that the AV produce written notification to the IACUC when an animal is placed on or removed from the exemption.
- The Principal Investigator (PI) may request an exemption from the IACUC based on scientific justification. In such cases, the exemption must be submitted to the IACUC for review and approval before its implementation. The exemption must be reviewed by the IACUC annually.
- Records of **any** exemptions must be maintained by the IACUC office and be made available to the appropriate regulatory authorities if requested.

Procedure:

- The request for a PI exemption (as described above) must be described and reviewed by the IACUC. It must be approved prior to instituting the deviation from standards. This exemption requires a description of the deviation(s), an estimate of the number of animals which will be covered by the deviation(s), and a strong scientific justification for why the existing standards are not adequate.
- The exemption is reviewed as often as appropriate (described above, but at least during annual review).
- IACUC-approved exemptions are maintained by the IACUC and will be made available for reference as needed.
- The PI is responsible for ensuring that the approved exemption is appropriate for the current and prospective research. If revisions to, including removal of, the approved exemption are needed, an amendment must be submitted to and approved by the IACUC.
- Exemptions involving USDA species are included in the USDA annual report, as appropriate.

References:

- (1) AWAR (9CFR, Part 3, Subpart A, §3.8 (d) (1), (2), and (3); Subpart D, §3.81 (e) (1), (2), and (3)).
- (2) US Gov Principles II and IX (see PHS Policy pg. 4-5; *Guide* Appendix B, pg. 199-200).
- (3) PHS Policy (IV.C.1).
- (4) OLAW Section D. "Protocol Review" FAQ #14.

Document Log

Version Number	Approval Date	Description of Changes
1	6/20/2011	Initial Policy created and approved
2	3/20/2017	IACUC Policy was modified to clarify responsibilities and updated with new guidance and regulatory information
3	10/19/2020	IACUC Policy was updated to include clarifications of procedures