

Institutional Animal Care and Use Committee		UNTHSC
Title: Review of Standard Operating Procedures and Exceptions		
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Approved by IACUC Date: November 14, 2023		

A. BACKGROUND INFORMATION

- a. The IACUC must review and approve activities on a project-specific basis, taking into account a number of factors, e.g., the aims of the study, consideration of alternatives, minimization of pain and distress. For routine aspects of research, IACUCs may approve Standard Operating Procedures (SOPs) that can be cited by investigators in their protocols in order to avoid repetition.
- b. All SOPs that are IACUC approved, including procedures that describe internal procedures, should be reviewed by the IACUC at appropriate intervals (at least once every three years) to ensure they are up-to-date.
- c. According to Principal IX of the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, “Where exceptions are required in relation to the provisions of these Principles...should be made...by an appropriate review group such as an institutional animal care and use committee.”
- d. All Exceptions are approved by the IACUC either through the Animal Care and Use Protocol, or through a Universal Exception.

B. RESPONSIBILITIES

- a. It is the responsibility of the IACUC to review SOPs according to this SOP.
- b. It is the responsibility of the IACUC to review Exceptions according to this SOP.

C. PROCEDURES

- a. The IACUC Administrator will keep a list of all SOPs and Universal Exceptions with their approval dates, revision dates (if applicable), review due dates and review dates.
- b. The review due date will be within the month of the three years after the last approval date.
- c. SOP Review:
 - i. When an SOP is due for review, the SOP will be reviewed by the IACUC Office and the IACUC Chair to determine if significant changes are needed. A consultant may be brought into this initial review, for their expertise based on the topic of the SOP.
 - ii. If significant changes are needed for the SOP, it will be placed on the agenda for discussion at the next convened IACUC meeting. All members will have access to the SOP to review prior to the meeting.
 - iii. If no changes or minor changes are needed, then the SOP will be sent to all members, in which they are given 3 business days to consider the SOP and call for full committee review, should they wish to discuss it at a fully

- convened meeting. At the end of the 3 business days, if no one calls for full committee review, the Chair will designate reviewer(s) to review the SOP, in which they can approve, require further modifications, or request for it to be reviewed at the fully convened IACUC meeting.
- iv. If any revisions are necessary, the SOP will be revised and subsequently approved. If no changes are necessary, the review is noted in the IACUC meeting minutes and the date of review documented on the list of SOPs. The review of the SOP will be due again in three years.
- d. Exception Review:
- i. When an Exception is described within the Animal Care and Use Protocol, it is reviewed during the triennial review of the protocol.
 - ii. When a Universal Exception is due for review, the IACUC Office and the IACUC Chair to determine if significant changes are needed. A consultant may be brought into this initial review, for their expertise based on the topic of the Universal Exception.
 - iii. If significant changes are needed for the Universal Exception, it will be placed on the agenda for discussion at the next convened IACUC meeting. All members will have access to the SOP to review prior to the meeting.
 - iv. If no changes or minor changes are needed, then the Universal Exception will be sent to all members in which they are given 3 business days to consider the Universal Exception, and call for full committee review, should they wish to discuss it at a fully convened meeting. At the end of 3 business days, if no one calls for full committee review, the Chair will designate reviewer(s) to review the Universal Exception, in which they can approve, require further modifications, or request of it to be reviewed at the fully convened IACUC meeting.
 - v. If any revisions are necessary, the Universal Exception will be revised and subsequently approved. If no changes are necessary, the review is noted in the IACUC meeting minutes and the date of review documented on the list of Universal Exceptions, where it will be due again for review in three years.

D. REFERENCES

- a. OLAW website, Frequently Asked Questions, PHS Policy on Humane Care and Use of Laboratory Animals, http://grants.nih.gov/grants/olaw/faqs.htm#proto_14 accessed 11/19/2014.
- b. [U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. Published in the Federal Register, May 20, 1985, Vol. 50, No. 97, by the Office of Science and Technology Policy \[FR Doc. 85-12059\].](#)