

IACUC POLICIES, PROCEDURES, and GUIDELINES

DOCUMENTATION OF IACUC ACTIVITIES

Purpose:

This document establishes guidelines for the documentation of the attendance, activities, and deliberations of the Institutional Animal Care and Use Committee (IACUC) of the University of Kentucky (IACUC Minutes).

Responsibilities:

The responsibility for the maintenance of records documenting the attendance, deliberations, and actions of the Institutional Animal Care and Use Committee is an Institutional responsibility. The Executive Secretary of the IACUC through the Office of Research Integrity (ORI) is responsible for documentation, preparation, and maintenance of the attendance, deliberations, and actions of the University of Kentucky IACUC. The IACUC is responsible for the review and final approval, by a majority vote at a convened meeting of a quorum of the IACUC, of all records of IACUC activities and deliberations.

General Guidelines:

IACUC Minutes

- Minutes of IACUC meetings must include:
 1. An attendance list including;
 - Full voting members
 - Alternate voting members and the member and membership category for which they are serving as the alternate
 - Alternate non-voting members
 - *Ex officio* non-voting members
 - Guests
 - IACUC and veterinary staff
 - If members of the IACUC leave the room due to a conflict of interest, such shall be recorded in the minutes.
 2. A listing of each protocol and significant amendment presented for IACUC consideration along with summary of the IACUC deliberations related to the protocol or significant amendment, including deliberations regarding the;
 - Rationale and purpose of the proposed use of animals.
 - Justification of the species and number of animals requested. Whenever possible, the number of animals requested should be justified statistically.

- Availability or appropriateness of the use of less-invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation
 - Adequacy of training and experience of personnel in the procedures used.
 - Unusual housing and husbandry requirements including exceptions to the regulations and standards, physical restraint, and food or water restriction.
 - Appropriate sedation, analgesia, and anesthesia. (Scales of pain or invasiveness might aid in the preparation and review of protocols)
 - Unnecessary duplication of experiments.
 - Conduct of multiple major operative procedures.
 - Criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated.
 - Post procedure care.
 - Method of euthanasia or disposition of animal.
 - Safety of working environment for personnel.
3. A record of the final IACUC actions regarding each presented protocol or significant amendment including
- Administrative changes made to the protocol, if any.
 - Results of the IACUC vote
 - Approval
 - List of specific modifications or clarifications required to secure approval, and
 - IACUC determination as to whether the final consideration and approval can be by a specific designated reviewer or if full IACUC consideration is necessary.
 - Withhold approval
 - Statement of the reasons the IACUC withheld approval, and
 - specific provisions for the investigator to respond, in writing or in person, to the reasons identified.
4. A record of IACUC discussions and deliberations regarding issues not directly associated with a specific animal use protocol including, but not limited to, those related to the Animal Care and Use Program and IACUC policies and procedures.
- The IACUC minutes should not be a transcription of the meeting but rather a record of the deliberations. Sufficient detail should be included to permit an

outside person to determine that the IACUC considered the relevant topics and to ascertain the nature of the IACUC's discussions and conclusions regarding major topics discussed. Minority opinions, when present, should be documented in the minutes.

- Individuals involved in the deliberations should not be specifically identified in the minutes.

Semiannual Facility Inspections and Program Review

- The semiannual facility inspection and program review report must include:
 1. A list of the date and the IACUC members present during the inspection of each animal housing site, each animal study site, and each investigator laboratory inspected and evaluated as a component of the semiannual facility and program review.
 2. A list of the date and the IACUC members present during the semiannual program review and evaluation.
 3. A description of the nature and extent of the institution's adherence to the *Guide for the Care and Use of Laboratory Animals*, the *Public Health Service Policy on the Humane Care and Use of Laboratory Animals*, and the *Animal Welfare Regulations*.
 - Departures from the requirements must be specifically identified and the reason for each departure stated.
 - A reasonable and specific plan and schedule for the correction of facility or program deficiencies must be provided.
 - The report must distinguish significant from minor deficiencies. A significant deficiency is one which in the judgment of the IACUC and the Institutional Official is or may be a threat to the health or safety of the animals.
 4. A list of facilities that are accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). Any changes in the accreditation status from the previous semiannual report must be noted.
- Each member must be provided the opportunity to include minority opinions and views in the semiannual facility inspection and program review report. If after the opportunity is provided no such reports are received, such shall be recorded in the semiannual facility inspection and program review report.
- The semiannual facility inspection and program review report must be signed by a majority of the IACUC members.

Regulatory Guidance:

- Animal Welfare Regulations, 9CFR, Chapter 1, Subchapter A
 - §2.35 Recordkeeping requirements.
 - (a) The research facility shall maintain the following IACUC records:
 - (1) Minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations;
 - (2) Records of proposed activities involving animals and proposed significant changes in activities involving animals, and whether IACUC approval was given or withheld; and
 - (3) Records of semiannual IACUC reports and recommendations (including minority views), prepared in accordance with the requirements of Sec. 2.31(c)(3) of this subpart, and forwarded to the Institutional Official.
- Public Health Service Policy on Humane Care and Use of Laboratory Animals, Office of Laboratory Animal Welfare, National Institutes of Health, August 2002

IV. E. Recordkeeping Requirements

1. The awardee institution shall maintain:
 - a. a copy of the Assurance which has been approved by the PHS;
 - b. minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations;
 - c. records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld;
 - d. records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official; and
 - e. records of accrediting body determinations.
2. All records shall be maintained for at least three years; records that relate directly to applications, proposals, and proposed significant changes in ongoing activities reviewed and approved by the IACUC shall be maintained for the duration of the activity and for an additional three years after completion of the activity. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

- *Guide for the Care and Use of Laboratory Animals*, National Academy Press, 1996

“The institution is responsible for maintaining records of the activities of the IACUC and for conducting an occupational health and safety program.” (pg 8)

“Records of committee meetings and of results of deliberations should be maintained.” (pg 9)

- PHS Policy on Humane Care and Use of Laboratory Animals - Frequently Asked Questions. Revised: February 26, 2008
http://www.grants.nih.gov/grants/olaw/faqs.htm#IACUC_7

“What information should be in IACUC minutes?”

PHS Policy requires that minutes of IACUC meetings, records of attendance, activities of the Committee, and Committee deliberations, be maintained by the institution. Accordingly there should be documentation of major issues discussed by the IACUC and the outcome of the discussions in sufficient detail for an outsider to ascertain the nature of the discussion and the conclusions reached. Written transcripts or tape recordings of meetings are not required. “

- *Animal Care Resource Guide, Research Facility Inspection Guide*, United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care
http://www.aphis.usda.gov/animal_welfare/downloads/manuals/rig/complete/rig_complete.pdf

“The IACUC records which must be maintained include, but are not limited to:

- minutes of the IACUC meetings, including:
 - a list of members who attended and/or did not attend
 - all the activities conducted by the IACUC at the meeting
 - substance of the deliberations of the IACUC, not just the decisions reached
 - any minority views
 - approval of the minutes (usually of the previous meeting) by the IACUC
- verification of appointment of IACUC members by the Chief Executive Officer (CEO)
- records relating to animal activities, including:
 - protocols
 - proposed significant changes to protocols
 - IACUC decisions on protocols and proposed changes
 - notification of Principal Investigator and Institutional Official of IACUC decisions on protocols and proposed changes
 - notification of suspension of protocol
 - annual review of protocols
- program of humane care and use
- semi-annual reports, including:
 - review of humane care and use program

- facility inspection
- report of program review to the Institutional Official, including minority views
- significant deficiency reports
- recommendation to the Institutional Official
- complaint investigations
- approved exemptions/exceptions to the regulations or standards

All records and reports must be maintained:

- at least 3 years, or
 - longer if:
 - necessary to comply with any applicable Federal, State, or local law
 - the APHIS Administrator notifies the research facility, in writing, that specified records must be retained pending completion of an investigation or proceeding
- NOTE: The APHIS Administrator will inform the research facility, in writing, when the records may be disposed of.”

Records must be held at least 3 years from the date:

- an animal is disposed of or euthanized
- of completion of the IACUC-approved protocol
- of completion of the IACUC-approved significant change to a protocol

Approved and Adopted by the
Institutional Animal Care and Use Committee
October 15, 2008