Office of Sponsored Programs & Research Integrity Guidance for Acquiring and Managing Externally Funded Projects and Research Compliance

Volume III Animal Subjects Research: Institutional Animal Care and Use Committee Procedures (IACUC)



Chapter 1: Purpose, Mission & Organization of the Institutional Animal Care and Use Committee (IACUC)

1.1 Purpose

The University of Central Missouri (UCM) Institutional Animal Care and Use Committee (IACUC) is dedicated to the humane care and use of animals in activities related to research and teaching conducted at UCM or by individuals associated with the university.

1.2 Mission

The IACUC is guided by federal regulations and ethical principles intended to ensure the humane care and use of animals in research and teaching.

1.3 Organizational Structure

UCM's IACUC reports to the Institutional Official (IO). The IACUC includes the committee, the Research Compliance Officer, and clerical support.

1.3.1 Institutional Official

The Institutional Official has the authority to legally commit, on behalf of UCM, that regulatory requirements will be met under the Animal Welfare Act (AWA) and Public Health Service Policy (PHS Policy). The IO is responsible for appointing members to IACUC, and as the IO, will sign UCM's Institutional Assurance.

1.3.2 IACUC Committee

The IACUC consists of at least seven members, of varying professional and personal backgrounds, including at least one veterinarian, one non-scientist, one practicing scientist, and one person who is not affiliated with UCM in any way other than as a member of the IACUC (for example, a community member). The community member may be either a scientist or non-scientist. As described in the Official Charge, the (IO) of UCM appoints the committee with recommendations from the IACUC Chairperson along with nominations from the Faculty Senate Committee on Committees for specific positions with confirmation by the Faculty Senate. A quorum is required at any meeting at which formal action is taken by the IACUC, and a majority vote of those present at the meeting is required for any formal action (for example, approval or suspension).

The IACUC has general oversight responsibility for the UCM IACUC Policies and Procedures, Occupational Health and Safety Program (OHSP), Veterinary Care Program, and the Animal Research Facility (ARF). Responsibilities of the IACUC include the review of animal use, inspection and review of ARF Standard 2 Operating Procedures, Veterinary Care Program, compliance activities, record keeping and community relations.

1.3.3 Attending Veterinarian

UCM's Attending Veterinarian ensures federal compliance in accordance with PHS Policy, AWA, and the Office of Laboratory Animal Welfare (OLAW) by routinely inspecting the animal facilities and all animals at UCM. The Attending Veterinarian provides routine veterinary care, preventive medical care, and oncall emergency care and consultation for UCM animals. The Attending Veterinarian has the authority to immediately halt activity on any protocol if animal welfare is endangered. If the Attending Veterinarian is not on campus, the animal care specialist is responsible for daily care and facility management.

1.3.4 Research Compliance Officer

The Research Compliance Officer is administrative personnel that ensures compliance with federal mandates.

Chapter 2: Protocol Review Process and Procedures

2.1 Activities Requiring IACUC Approval

The following activities involving live animals must be approved by the IACUC before any action is initiated:

2.1.1 UCM Facilities

All research, teaching, biological testing projects and breeding work conducted by anyone at UCM regardless of the source of funding. Exception to this includes the UCM farms which house animals for agricultural and agricultural education purposes only.

2.1.2 UCM Personnel

All research, teaching, biological testing projects and breeding work conducted at another institution or elsewhere by faculty, students, staff, or other representatives of UCM in connection with the investigator's institutional responsibilities. The IACUC may accept oversight of the animal use by another PHS-approved IACUC.

2.2 Activities Not Requiring IACUC Approval

- The study of animals in their natural habitat without investigator intervention;
- The study of preserved specimens or tissues obtained from recognized vendors of scientific supplies, research institutions or museums;
- The study of tissues obtained from a USDA-approved slaughterhouse or any vendor selling such tissue;
- Any activities not associated with teaching or research.

Chapter 3: Categories of Animal Use

IACUC categorizes animal use based on the purpose of the animal use and the extent of pain, discomfort or distress anticipated for the animals. Additional information on these four categories can be found in the application instructions.

3.1 Categories Paralleling USDA Designations:

3.1.1	Category B
	Breeding that involves no procedures or functional deficits that may cause more than momentary or slight pain, discomfort, or distress.
3.1.2	Category C
	Research or teaching that involves no procedure or functional deficits that may cause more than momentary or slight pain, discomfort, or distress.
3.1.3	Category D
	Research, teaching or breeding that has the potential to cause more than momentary slight pain, discomfort or distress that will be alleviated with appropriate anesthesia, analgesia or tranquilizers; and/or that involves chronic maintenance of animals with a minor to moderate functional deficit.
	Category E
	Research, teaching or breeding involving more than momentary pain, discomfort or distress that cannot or will not be alleviated through the administration of appropriate anesthetics, analgesics, or tranquilizers; and/or that involves chronic maintenance of animals with a severe functional deficit.

Chapter 4: Animal Incident Reporting

4.1 Unanticipated or Atypical Events

During the course of an IACUC approved research activity, an unanticipated or atypical event (including death of the animal) may occur. Such Animal Incidents are, by definition, occurrences that are not discussed in the Protocol covering the animal work. An unanticipated event is a serious event that impacts animal welfare and that may re-occur

if no changes in procedures occur; examples would be unexpected complications from a surgical procedure, or injuries to animals during handling. An atypical event is generally a truly chance event that would not have been avoidable despite reasonable precautions; examples would be the loss of an animal due to an equipment failure or rare congenital condition.

4.2 Animal Incidents

If any Animal Incident occurs, personnel present at the event should immediately contact ARF personnel and/or the Attending Veterinarian if advice or assistance could reduce animal suffering or prevent a recurrence of the Incident. In all cases, an Animal Incident Report must be completed within 72 hours of the event and submitted electronically to the ARF Manager and IACUC Office. The Report describes the nature of the Incident and a Plan of Action to prevent recurrence, if appropriate. If a finalized Report cannot be submitted within 72 hours of the Incident, and initial Report should be submitted by this deadline with a follow-up Report submitted as soon as possible thereafter. The Report(s), including the Plan of Action, are reviewed by the Attending Veterinarian, ARF Director or designee, and the IACUC. Principal Investigators are reminded that any Plan of Action involving changes to procedures described in a Protocol will require an approved modification of the Protocol. Failure to report an initial Animal Incident Report within 72 hours may result in corrective action by the IACUC and/or ARF.

Chapter 5: Semiannual Review and Post-Approval Monitoring

Twice each year the IACUC reviews the UCM's IACUC Policies and Procedures for animal care and use programs and inspects all UCM facilities where animals are housed and/or used. A subcommittee of the IACUC, composed of at least four members, to include the Chair and Attending Veterinarian shall conduct the semiannual reviews. No IACUC member wishing to participate in any review shall be excluded. The subcommittee may invite ad hoc consultants to assist in the reviews.

5.1 Types of Semiannual Review

5.1.1 Review of the IACUC Policies and Prod

The IACUC is required to semiannually evaluate the UCM's IACUC Policies and Procedures for animal care and use programs. This semiannual evaluation includes the following:

- IACUC membership and functions, including protocol review practices
- IACUC records and reporting requirements
- Veterinary care, to include:
 - Preventive medicine, animal procurement, and animal transportation

- Surgery
- Pain, distress, analgesia, and anesthesia
- o Euthanasia
- Drug storage and control
- Personnel qualifications and training
- Occupational health and safety of personnel
- ARF Disaster Plan
- The IACUC has developed specific semiannual audit forms and uses a Program and Facility Review Checklist as a guide when conducting its review.

5.1.2 Review and Inspection of Animal Facilities

A semi-annual inspection of the Institution's animal facilities, using the 8th edition of The Guide as a basis for evaluation, will occur at least once every six months. The IACUC procedures for conducting semiannual facility inspections are as follows: No member who wishes to participate will be excluded from doing so. Any member who cannot attend the semiannual meeting will be encouraged to complete an inspection of the animal facilities via appointment with animal care staff. Results of the inspections are reported to the IO and IACUC Chair. Annual reports are also submitted to federally regulated governing bodies.

5.1.3 Monitoring of Corrective Action Plans

The IACUC shall provide a copy of the final semi-annual inspection to the Research Compliance Officer. The Research and Compliance Officer monitors deficiencies listed in the inspection report to ensure they are corrected in a timely manner.

Chapter 6: Programmatic Deficiencies and Corrective Actions

The IACUC semiannual evaluations are tools for institutional self-identification and correction of facility and program deficiencies. Program deficiencies include:

- Failure to correct situations identified as significant deficiencies in a timely manner
- Shortcomings in the programs of veterinary care, occupational health, training, or with the IACUC
- Conditions that jeopardize the health or well-being of animals, including accidents, natural disasters and mechanical failures resulting in actual harm or death to animals.

Programmatic deficiencies must be categorized as acceptable, minor, or significant. The corrective action for a significant deficiency must include a reasonable plan to correct the issues as well as a date by which the issue will be corrected. Significant programmatic deficiencies must be reported to the applicable regulatory agencies if the deficiency jeopardizes the health and welfare of the animals, or if UCM is unable to make the correction by the specified date.

The IACUC, through the IO or the IO's designee, shall promptly report to OLAW circumstances and actions taken with respect to:

- Any serious or continuing noncompliance with PHS Policy
- Any serious deviation from the provisions of The Guide
- Any suspension of an activity by the IACUC
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6.1 Agency-Specific Reporting Requirements

6.1.1 Office of Laboratory Animal Welfare (OLAW)

The IACUC, through the IO or the IO's designee(s), must contact the office of the Director of Compliance at OLAW immediately after:

- Suspension of any activity by the IACUC
- A finding of serious or continuing noncompliance with the PHS Policy
- A finding of significant deviation from the provisions of the Guide

After review of any allegation of non-compliance by the IACUC and the IO or the IO's designee(s), a formal written report will be filed with OLAW within three months of the event stating a full explanation of circumstances, a description of corrective actions taken, any minority views filed by the IACUC, and the status of the research program. A notification will be made to other federally regulated bodies as well.

6.1.2 Federal Funding Agencies

The IACUC, through the IO or the IO's designee(s), must contact any Federal agency funding an activity involving the use of animals immediately in the following instances:

- The activity is suspended by the IACUC
- The institution fails to adhere to a plan to correct a significant deficiency that affects the activity

6.2 Non-reportable Incidents

6.2.1 Examples of Incidents Normally Not Required to Report

- The death of animals that have reached the end of their natural life spans
- The death or failures of neonates to thrive when husbandry and veterinary medical oversight of dams and litters was appropriate
- Animal death or illness from spontaneous disease when appropriate quarantine, preventive medical, surveillance, diagnostic, and therapeutic procedures were in place and followed
- Animal death or injuries related to manipulations that fall within parameters described in the IACUC-approved protocol
- Infrequent incidents of drowning or near-drowning of rodents in cages when it is determined that the cause was water valves jammed with bedding (frequent problems of this nature, however, must be reported promptly along with corrective plans and schedules)

6.2.2 Advise Regarding Wildlife Found Injured in the Field

The Missouri Department of Conservation agents advise that regarding wildlife found injured in the field that is not a result of the research protocol:

- They request that researchers do not interact or interfere with injured wildlife.
- Only call authorities (appropriate county MDC agent or Sheriff) if species is listed as endangered.
- They may or may not let the landowner know of presence of injured animal, however, MDC cautions that not all wildlife appearing injured are injured.
- A dead/dying animal still maintains a role in the ecosystem and MDC would rather it be left alone unless listed as endangered.
- MDC feels that, lacking significant data showing otherwise, a baited camera trap does not imply that an injured animal in the vicinity was attracted by the bait and wasn't simply there by chance.

Chapter 7: Reporting Noncompliance

The IACUC investigates reports of noncompliance involving the care and use of animals.

Anyone who has concerns or questions about animal care and use at UCM, should contact the Research Compliance Officer, IACUC Chair or the ARF Manager. Anyone wishing to remain anonymous may complete the noncompliance form found on the IACUC website. UCM policy prohibits retaliation against any employee who makes a good faith report of known or suspected noncompliance in the care and use of animals.

Chapter 8: Investigation of Animal Care and Use Concerns

8.1 Initial Evaluation and Actions

When noncompliance is detected, the attending veterinarian will be notified. The attending veterinarian has authority to immediately halt activity on a protocol if he or she has reason to believe that animal welfare is being compromised. The Attending Veterinarian immediately notifies the affected Principal Investigator and the IACUC Chair in writing.

Upon receipt of a concern from any party, the IACUC Chair or his/her designee may convene an emergency meeting of the IACUC to determine whether the concern requires further investigation and immediate action, further investigation but no immediate action, or no action.

Veterinary medical intervention, suspension of a research activity, and/or notification of appropriate safety, occupational health, or other officials, are examples of actions that may be taken immediately. Situations that involve potential criminal activity or human safety are reported promptly to UCM's Public Safety or occupational health and safety officials. If immediate action is warranted to protect animal or human welfare, the IACUC notifies the IO or the IO's designee(s). Any formal suspension of activity is reported to regulatory agencies.

8.2 Suspension of a Protocol

The IACUC may suspend activities on a protocol if it finds violations of the Institutional Policy, PHS Policy, the Assurance, or Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and with the affirmative vote of a majority of the quorum present. If the IACUC suspends an activity involving animals, the IO in consultation with the IACUC shall review the reason for suspension.

The IO or the IO's designee(s) is required to take appropriate corrective action and report the action to regulatory agencies with full explanation.

8.3 Procedures for Reporting by the Research Compliance Officer

The Research Compliance Officer is responsible for reporting unanticipated problems involving risks to researchers or the care and use of animals; any serious or continuing noncompliance with 45 CFR Part 36 or the requirements or determinations of the IACUC; and any suspension or termination of IACUC approval. The Research Compliance Officer is responsible for reporting any such events to: the IACUC, the IO, the dean of the appropriate school, any agency or department which is funding the research; and OLAW.

Such reporting will take place no more than five business days after a determination has been made that one of the events described above has occurred.

8.4 Actions by the IACUC in Response to Unanticipated Problems

In the event of unanticipated problems involving risks to animals or others, the IACUC will evaluate the nature of the problems and decide on appropriate action, which could range from temporarily suspending the research project to terminating approval for the project and requiring the investigator(s) and appropriate IOs to resolve the problems.

8.5 IACUC Response to Serious or Continuing Noncompliance

Guidelines for the procedure for the investigation of allegations of scholarly or scientific misconduct are outlined in the Ethics Policy (1.2.180) found in UCM's University Policy Library. The IACUC may informally gather and process information to evaluate the nature of the IACUC problem for the purpose of determining course of action.

8.6 Range of Possible Actions

Appropriate action could range from requiring appropriate educational activities to recommending official reprimand of the investigator(s), listing the investigator(s) as ineligible to conduct research with animals at UCM, or recommending termination of employment.

Chapter 9: Reporting and Recordkeeping

9.1 Public Health Service Assurance

The IACUC is responsible for completing the PHS Assurance. The IACUC may seek input from the ARF Director, General Counsel and other individuals as necessary to complete these documents. The PHS Assurance is renewed every five years. The PHS Assurance is signed by the IO and submitted to the appropriate agency by the IACUC.

9.2 PHS/OLAW

At least once every 12 months the IACUC, through the IO, shall submit a written report, to include any minority views, to OLAW. The report shall include the following:

- Changes to UCM's program or facilities that would place it in a different category than specified in our Assurance;
- Changes in the IACUC membership;
- Changes in the description of UCM's IACUC Policies and Procedures for animal care and use programs as outlined in the Assurance;
- Dates that the IACUC conducted its semiannual evaluations and submitted its reports to the IO.

If there are no changes, the report shall state that there are no changes and shall inform OLAW of the dates of the semiannual evaluations and submission of semiannual reports to the IO.

9.3 Semiannual reports

Upon completion of semiannual reviews, the IACUC shall submit written semiannual reports to the IO.

9.4 Record Keeping Requirements

The IACUC shall maintain applications and modification forms submitted for review; minutes of meetings, including records of attendance; activities of the IACUC and deliberations, records of proposed activities, and proposed significant changes, including whether the IACUC approval was given or withheld; records of semiannual reports and recommendations; and UCM's Assurance, and annual reports to government agencies. These records shall be retained as follows:

- Five-Year Retention The IACUC shall retain the Assurance for at least five years or until a new Assurance is approved, whichever is longer.
- Three-Year Retention The IACUC shall retain the following records for at least three years:
 - o Records of semiannual IACUC reports and recommendations,
 - Records of animals,
 - Records of any accrediting body determinations, if applicable,
 - Annual reports,
- Other The IACUC shall retain records relating to proposed activities and significant changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and three years after the end of the activity. Such records include, but are not limited to, records of applications, modifications, minutes of IACUC meetings, and records of investigations of noncompliance related to an approved protocol.

9.5 Animal Resource Facility Disaster Plan

The IACUC ensures that the ARF maintains an effective plan to respond to crisis events. The ARF follows disaster/crisis protocol as outlined in UCM's Emergency Operation Plan, which is managed by UCM's Office of Environmental Health and Safety.

The IACUC abides by the following regulations and governing bodies:

If you'd like to know more, please click on the links above. You may contact the Research Compliance Officer or IACUC Chair with questions. Public Health Service Policy on Humane Care and Use of Laboratory Animals Office of Laboratory Animal Welfare Animal Welfare Act Occupational Health and Safety in the Care and Use of Animals The Guide 8th ed.

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