University of Michigan Policy & Procedures Concerning the Use of Vertebrate Animals as Subjects in Research, Testing, or Instruction

The Policy

The policy of the University of Michigan is to ensure humane use and care of vertebrate animals used in research, instruction, and testing, and to adhere to applicable laws, regulations, policies, principles, and standards (including accreditation) affecting such use. (See listing at www.animalcare.umich.edu)

Applicability

University policy and procedures shall apply in all situations and activities of the University in which vertebrate animals are used in research, testing, instruction, or other activities, regardless of the source(s) of support. They shall apply equally whether the supporting funds are from outside or from within the University, whether separately budgeted or non-budgeted.

Implementation and Administration

The institutional program for compliance with this policy is the responsibility of the Vice President for Research (Institutional Official, IO). The Institutional Official has delegated to the Deputy Institutional Official (DIO) and the Attending Veterinarian the responsibility for monitoring the Animal Care & Use Program, for provision of veterinary care, and for administrative and technical support of the Animal Care & Use Program University-wide.

The University has established an Institutional Animal Care & Use Committee (IACUC), which is qualified through the experience and expertise of its members to advise, monitor, inspect, and oversee the University's animal program, facilities, and procedures. The "Charge to the Institutional Animal Care and Use Committee" (available at www.animalcare.umich.edu) specifies its composition and general charge.

The IACUC shall review each activity involving vertebrate animals for humane use and for compliance with applicable laws, regulations, policies, principles, and standards affecting such use.

Application for Approval

Prior to the acquisition of any vertebrate animal for use in research, instruction, testing, or other activity, the Principal Investigator, Course Director, or responsible faculty member shall submit to IACUC a completed Animal Use Application (Animal Protocol). Vertebrate animals may not be acquired nor any activity involving vertebrate animals begun until written approval is received from IACUC.

IACUC Review

Each IACUC member shall be provided with access to all applications to be reviewed. Members shall review the applications during a designated review period, and indicate their approvals or issues of concern before the end of that period. Reviewer concerns shall be communicated to the applicant, and his/her response returned to the designated reviewer for further consideration. Once all outstanding issues are resolved to the satisfaction of

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reviewers, the application can be approved. At any time during this process, any member may call for review of an application at a convened meeting of the IACUC. Applications reviewed at a convened IACUC meeting may be approved, denied approval, or require modification by majority vote of a guorum of members.

Withholding of Approval

The IACUC may withhold approval of an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the consent of a majority of the quorum present. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the Principal Investigator or Course Director an opportunity to respond in person or in writing. The IACUC may reconsider its decision, with documentation in Committee minutes, in light of the information provided by the Principal Investigator or Course Director.

Further Review

Applications and proposals that have been approved by the IACUC may be subject to further appropriate review and approval by University officials. However, those officials may not approve an application if it has not been approved by the IACUC.

Changes in Procedures

The Principal Investigator or Course Director shall secure approval from the IACUC prior to implementing significant changes in procedures or expected outcomes during the course of the activity. Examples of significant changes include, but are not limited to, the following: (1) increase in severity of adverse consequences experienced by the animals; (2) addition of or change in species of animal; (3) increase in the number of animals required; (4) addition of or change in animal use procedures; and (5) change in principal investigator. Many seemingly minor changes can significantly affect animals. The Animal Care & Use Office should be contacted for guidance on whether a proposed change should be submitted for review and approval.

Suspension of an Activity

The IACUC may suspend an activity that it previously approved if the IACUC determines that the activity is not being conducted in accordance with this Policy and the approved animal protocol. The matter must be reviewed at a convened meeting of a quorum of the IACUC. The suspension requires a majority vote of a quorum present.

If the IACUC suspends an activity involving animals, the IO, in consultation with the DIO and IACUC, shall review the reasons for suspension, take appropriate corrective action, and report the suspension and corrective action to authorities in accordance with applicable laws, regulations, policies, and standards.

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Monitoring

Periodically, the IACUC shall monitor the animal care and use program and facilities, including animal use activities, for continuing compliance with this Policy. Matters related to compliance shall be brought to the IACUC for resolution according to associated policies.

If conditions are discovered that may be a threat to the health and safety of the animals, the Attending Veterinarian will consult with the DIO and the IACUC Chair or Vice-Chair, as time allows, and take immediate steps to rectify the situation. This can include suspension of all or part of protocol activities. A full report on the situation will be submitted to the IACUC and to the Institutional Official as soon as practical thereafter.

Serious or ongoing incidents of non-compliance with this Policy shall be addressed by the IACUC according to the steps outlined in the "UM IACUC Program for Rectifying Serious or Ongoing Non-Compliance in the Management of University Animal Care and Use" (www.animalcare.umich.edu).

Guidelines

Copies of applicable laws, regulations, policies, principles, and standards regarding the humane use and care of vertebrate animals used in research, instruction, and testing will be available from the Animal Care & Use Office. Additional supplemental information, intended to assist Principal Investigators and Course Directors in complying with this Policy, will also be available from the Animal Care & Use Office and at www.animalcare.umich.edu.

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