



TITLE: Suspension or Termination and Reinstatement of Animal Use Privileges and/or Protocols by the IACUC

Purpose: FIT considers the humane and ethical use of animals in research, teaching, and outreach activities a privilege, not a right. This privilege is extended to faculty, scientists, students, and staff when a PI obtains approval of a protocol by the FIT IACUC. A PI maintains this privilege by adhering to all relevant animal program rules and requirements and by demonstrating a continuous commitment to animal welfare. The USDA Animal Welfare Act Regulations and the Public Health Service Policy on the Humane Care and Use of Laboratory Animals empower IACUCs to protect animals and institutional principles of ethical animal use by suspending or terminating an individual's privilege to use live, vertebrate animals. Documentation of the source of authority for these activities is found in Appendix 1. Suspension or termination of animal activities and/or protocols are infrequent but significant events. The following are guidelines regarding IACUC activity leading to, and following, suspension or termination.

Definitions:

1. **Suspension of previously approved animal use privileges:** An action initiated by the attending veterinarian or IACUC to temporarily stop specified animal activities pending future review and action by the IACUC.
2. **Suspension of a previously approved protocol for cause:** An action initiated by the attending veterinarian or IACUC to temporarily stop some or all protocol-related animal activities pending future review and action by the IACUC.
3. **Termination of previously approved animal use privileges:** An action initiated by the attending veterinarian or IACUC to permanently stop specified animal activities based on a review of the facts and majority vote by the IACUC.
4. **Termination of a previously approved protocol for cause:** An action initiated by the attending veterinarian or IACUC to permanently stop some or all protocol-related animal activities based on a review of the facts and majority vote by the IACUC.
5. **Transfer of animals to husbandry protocols:** Animals assigned to a suspended or terminated protocol must be reassigned immediately to the holding protocol maintained by the academic unit in which the animals are housed or to another IACUC-approved protocol. If corrective actions are made within 7 days of notification of noncompliance, associated animals may be retained without transfer to the holding protocol with IACUC approval. Failure to correct noncompliance within 7 days of notification will result in the transfer of animals to the holding protocol.
6. References to communications made in writing are understood to include email correspondence.

PROCEDURE:

When considering suspension or termination:

1. IACUC closed session discussion regarding alleged inappropriate behavior or noncompliance by a PI/student/staff/instructor (the “individual concerned”) will be held within 7 days from the date of allegation and will begin with a description of the alleged infraction(s). If possible, the individual concerned should be allowed to address the committee during the discussion, although immediate animal welfare concerns must take precedence. It may be prudent to call the University’s Office of Human Resources and request that a representative from OHR be present for the IACUC’s discussion.
2. If the IACUC believes that an infraction has occurred, it may develop a motion to suspend or terminate animal use privileges and/or a protocol. The motion should cite specific grounds for the action and conditions under which suspended or terminated privileges and/or protocols might be reinstated. It also must include the time at which the action takes effect and the duration of the action if applicable. The motion should be read to the IACUC prior to a vote.
3. During discussion of protocol suspension or termination, IACUC members are directed to consider the following:
 - a. The disposition of animals assigned to that protocol, in the case of protocol suspension.
 - b. Whether the protocol can be assigned to a different PI in good standing, in the case of revocation of privileges.
 - c. Conditions under which individuals associated with the protocol but not under investigation could continue animal work, in the case of termination of animal use privileges.
4. All discussion must be documented in approved IACUC minutes.

Following a vote to suspend or terminate animal use privileges and/or a protocol:

1. IACUC action, including grounds for that action and any conditions for reinstatement, must be described in an official letter from the IACUC Chair to the individual concerned. A copy of the letter will be sent to the relevant supervisor (e.g. PI and/or Department Chair), Dean, and IO.
2. As required by law or regulation, OLAW, USDA, or other agency must be notified of the action taken.
3. Requests for clarification or reconsideration of the action from the individual concerned must be made in writing to the IACUC Chair. The individual concerned may ask to address the committee in person, in which case this item will be added to the agenda for the next IACUC meeting’s closed session.
4. If a PI’s animal use privileges are suspended, the PI’s protocol could be maintained by identification of a replacement PI. This action requires a protocol amendment and IACUC consideration and approval.
5. If a protocol is suspended, its animals must be reassigned (such as to an appropriate holding protocol or another PI’s protocol) or euthanized. The IACUC Chair and Attending Veterinarian will consult with animal program staff to identify appropriate assignment.

Reinstatement of animal use privileges and protocols:

1. The individual concerned must request reinstatement in writing to the IACUC Chair. He/she must provide written evidence that all requirements for reinstatement have been met. The individual concerned also must provide a written plan that describes how the activities that led

to the suspension or termination will not be repeated. The committee must respond to the request at the next IACUC meeting.

2. A motion to reinstate suspended or terminated privileges and/or protocols, which should include additional IACUC recommendations such as extended oversight, must be made by a voting member of the IACUC. The reinstatement motion must include the time at which the reinstatement takes effect. The motion should be read to the IACUC prior to a vote. The motion, discussion, and vote must be documented in approved minutes.

Appendix 1

The following summarization is intended to provide the Animal Care and Use Committees (ACUCs) with a synopsis of the sources which provide the committee with the authority to suspend or terminate the animal use related activities covered in this SOP.

Relevant Authorities: The USDA Animal Welfare Act Regulations (AWARs) and the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) charge Institutional Animal Care and Use Committees (IACUCs) with the responsibility and authority to:

- Suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the approved protocol, the AWARs, the Guide for the Care and Use of Laboratory Animals, the institution's PHS Assurance, or the PHS Policy. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. AWAR ss. 2.31(c)(6) and (d)(6); PHS Policy ss. IV.B.8., IV.C.6.
- Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes in an approved protocol regarding the care and use of animals in ongoing activities. AWAR sec. 2.31(c)(7); PHS Policy sec. IV.B.7.
- Review, and, if warranted, investigate concerns involving the care and use of animals in teaching, research or outreach resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees. AWAR sec. 2.31(c)(4); PHS Policy sec. IV.B.4.

The AWARs and PHS Policy further provide that:

1. An institution's attending veterinarian shall have appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and to suspend an activity utilizing animals immediately based on analysis of the situation. AWAR sec. 2.33(a)(2).
2. If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity. AWAR sec. 2.31(c)(7); PHS Policy sec. IV.C.7.
3. The IACUC shall notify principal investigators in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval. 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 an opportunity to respond in person or in writing. AWAR sec. 2.31(d)(4); PHS Policy IV.C.4.

4. The IACUC may reconsider its decision, with documentation in Committee minutes, in light of the information provided by the principal investigator. AWAR sec. 2.31(d)(4).
5. Proposed activities and proposed significant changes in ongoing activities that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the research facility. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC. AWAR sec. 2.31(c)(8); PHS Policy IV.C.8.

Further amplifying and clarifying the AWARs and PHS Policy is the federal and university guides and policies. This includes: The Guide for the Care and Use of Laboratory Animals, 8th Edition, which confirms that using animals in research is a privilege granted by society to the research community.

Approved by the IACUC 29 July 2015

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