



TITLE: Suspension or Termination and Reinstatement of Activities Using Animals by the Institutional Official (IO)

Purpose: The USDA Animal Welfare Act Regulations (AWARs) and the Public Health Service Policy on the Humane Care and Use of Laboratory Animals (PHS Policy) define the role of the Institutional Official (IO) as the individual who is authorized to commit on behalf of the research facility that animal welfare regulations will be met. The AWARs and PHS Policy do not preclude any IO or institutional sanctions. Therefore, although action to suspend or terminate activities will normally be handled by the IACUC, the IO also has the authority to suspend activities using animals (see definition below). Documentation of the source of authority for these activities is found in the Appendix.

Suspension or termination of activities using animals

It is the expectation that at such time that the IO considers taking action to suspend or terminate activities using animals, or impose sanctions to address misconduct that does not affect animal welfare but those sanctions will impact activities using animals, the IO will follow this Procedure to ensure animals are protected and all matters of due process are honored, including defining a path to reinstatement of activities using animals. This document is designed to facilitate implementation of Non-Compliance procedures.

Definitions:

1. Activities using animals are understood to mean any circumstance in which an animal is handled, manipulated, maintained, or observed directly or indirectly within the FIT animal program as described in an IACUC-approved protocol, Standard Operating Procedure, or veterinary standard for the purposes of research, teaching, or outreach. These activities can be a specific manipulation(s) in a protocol, all manipulations in a protocol (the entire protocol), or an individual's overall ability to work with animals in any capacity (privilege to use animals).
2. Attending Veterinarian (AV): The veterinarian employed by FIT.
3. Suspension of activities using animals: An action to stop temporarily specified activities using animals. Such action may be taken by the IACUC, AV, or IO.
4. Termination of activities using animals: An action to stop permanently specified activities using animals taken by the IO in his/her institutional role. The IACUC may take action to terminate activities with animals. The AV cannot independently take action to terminate activities using animals.
5. References to communications made in writing are understood to include email correspondence.

PROCEDURE: When considering suspension or termination:

1. Discussions regarding alleged inappropriate behavior or non-compliance by a principal investigator/student/staff/instructor (the "individual concerned") must be in consultation with the IACUC.

2. Such discussions should begin with a description of the alleged infraction(s). The individual concerned should be solicited for information, however, immediate animal welfare concerns and institutional integrity must be priorities.
3. If the IO believes there is reason to suspend or terminate activities using animals, the following should be considered and planned for with input from the AV and IACUC prior to action:
 - a. The disposition of animals assigned to protocols, in cases of suspension or termination of all activities using animals (e.g., an entire protocol or protocols).
 - b. If there are students who could be disadvantaged by such action.
 - c. Whether the protocol can be assigned to a different PI that is in good standing, in the case when suspended or terminated activities using animals includes the removal of an individual's ability to use animals in any capacity, rendering that individual ineligible to be PI on a protocol.
 - d. Conditions under which individuals associated with protocol(s) but not under investigation could continue animal work, in the case of suspension or termination of all activities using animals (e.g., an entire protocol or protocols).
 - e. Effective date and duration of the suspension of privileges.
 - f. Terms of reinstatement of activities using animals if applicable.
4. All discussion must be documented.

Following IO action to suspend or terminate activities using animals:

Action to suspend or terminate, including grounds for that action and any conditions for reinstatement of activities using animals as decided in conjunction with the IACUC, must be described in an official letter from the IO to the individual(s) concerned. The IO may draw from any institutional resources available to facilitate reinstatement to ensure animals are protected and all matters of due process are honored. Reinstatement of activities using animals must be coordinated with and facilitated by the IACUC.

Approved by the IACUC 14 July 2015; Author(s): S. Emer, C. Bashur

Appendix

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

1. Legally commit on behalf of the research facility that animal welfare regulations will be met. AWAR sec. 1.1.
2. Sign, and have authority to sign the institution's Assurance, making a commitment on behalf of the institution that the requirements of the PHS policy will be met. PHS Policy sec. III.G.

3. Receive recommendations from the Institutional Animal Care and Use Committee (IACUC) regarding any aspect of the research facility's animal program, facilities, or personnel training. AWAR sec.2.31(c)(5); PHS Policy IV.B.4.
4. Review the reasons for suspension, take appropriate corrective action in consultation with the IACUC, and report the suspension and corrective action to appropriate federal agencies, when the IACUC suspends an activity involving animals. AWAR sec. 2.31(c)(7); PHS Policy sec. IV.B.7.
5. Subject activities approved by the IACUC to further review and approval. AWAR sec. 2.31(c)(8); PHS Policy sec. IV.B.8. Further amplifying and clarifying the AWARs and PHS Policy are various federal and university guides and policies. These include: 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. The adoption of the Guide as standard is an established FIT IACUC procedure.