Standard Operating Procedures for Suspension or Termination and Reinstatement of Activities Using Animals or Animal Use Privileges by ACUCs (adopted May 2, 2011; amended October 2018: amended December 16, 2020)

Background:

The University 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 Principal Investigator (PI) obtains approval of a protocol by one of the UW-Madison Animal Care and Use Committees (ACUCs). 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 Institutional Animal Care and Use Committees to protect animals and institutional principles of ethical animal use by suspending or terminating activities using animals (see definition below). Documentation of the source of authority for these activities is found in Appendix 1.

Suspension or termination of activities using animals or animal use privileges

Suspension or termination of activities using animals or animal use privileges are infrequent but significant events. The following are guidelines regarding ACUC activity leading to, and following, suspension or termination. This document is designed to facilitate implementation of Protocol Non-Compliance, <u>UW-4113</u> and the relevant authorities referenced therein. Examples of activities that may result in suspension of activities or animal use privileges using animals are described in Handling and Treatment of Animals (<u>UW-4119</u>).

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 UW-Madison animal program as described in an ACUC-approved protocol, ACAPAC- or ACUC-approved policy, 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, or all manipulations in a protocol (the entire protocol).
- 2. **Animal Use Privileges:** The privilege to use living, vertebrate animals for research, teaching, or outreach is the eligibility of an individual to work, or supervise work, with animals in any capacity. Suspension of this privilege may be enacted in conjunction with suspension of animal activities or independently.
- 3. Attending Veterinarian (AV): The Chief Campus Veterinarian (CCV) or a Senior Program Veterinarian (SPV) employed by the Research Animal Resources and Compliance (RARC) or Wisconsin National Primate Research Center (WNPRC).
- 4. **Suspension of activities using animals:** An action to stop temporarily specified activities using animals. Such action may be taken by the ACUC, AV, or IO.
- 5. **Suspension of animal use privileges:** An action to stop temporarily the overall eligibility of an individual to work, or supervise work, with animals in any capacity. Such action may be taken by the ACUC, AV, or IO.
- 6. **Termination of activities using animals:** An action to stop permanently specified **activities using animals** based on a review of the facts and majority vote by the ACUC. The IO may take independent action to terminate activities using animals, please refer to the IO SOP in this situation. The AV cannot independently take action to terminate

- activities using animals.
- 7. **Termination of animal use privileges:** An action to stop permanently the overall eligibility of an individual to work, or supervise work, with animals in any capacity based on a review of the facts and majority vote by the ACUC, or by the IO. This action is not equivalent to termination of employment.
- 8. **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 ACUC-approved protocol.
- 9. References to communications made in writing are understood to include email correspondence.

When considering suspension or termination:

- 1. ACUC closed session discussion regarding alleged inappropriate behavior or non-compliance by a principal investigator/student/staff/instructor (the "individual concerned") should 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 ACUC's discussion.
- 2. If the ACUC believes that an infraction has occurred, it may develop a motion to suspend or terminate activities using animals or animal use privileges. The motion should cite specific grounds for the action and conditions under which suspended or terminated activities using animals or animal use privileges 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 ACUC prior to a vote.
- 3. During discussion of protocol suspension or termination, ACUC members are directed to consider the following:
 - 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. Conditions under which individuals associated with protocol(s) but not themselves under investigation could continue animal work (e.g. under another PI; under a different protocol) in the case of suspension or termination of all activities using animals (e.g., an entire protocol or protocols).
 - c. In a case where the animal use privileges of a PI are suspended or terminated, whether the protocol can be assigned to a different PI that is in good standing.
 - d. All discussion must be documented in approved ACUC minutes.

Following a vote to suspend or terminate activities using animals or activities using animals: ACUC action, including grounds for that action and any conditions for reinstatement, must be described in an official letter from the ACUC Chair to the individual concerned. A copy of the letter will be sent to the relevant supervisor (e.g. Pl and/or Department Chair), Dean, and IO.

- 1. OLAW, USDA, or other agency or entity must be notified of the action taken if such notification is required by law or regulation.
- 2. Requests for clarification or reconsideration of the action from the individual concerned must be made in writing to the ACUC 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 ACUC meeting's closed session.
- 3. If a PI's privilege to use animals is suspended or terminated, the PI's protocol could be

- maintained by identification of a replacement PI. This action requires a protocol amendment and ACUC consideration and approval.
- 4. If activities using animals are suspended, as needed, animals must be reassigned (such as to an appropriate holding protocol or another Pl's protocol) or euthanized. The ACUC Chair and Attending Veterinarian will consult with animal program staff to identify appropriate assignment.

Reinstatement of activities using animals or animal use privileges:

- The individual concerned must request reinstatement in writing to the ACUC 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 ACUC meeting at which a voting quorum is
 present.
- 2. A motion to reinstate suspended or terminated activities using animals or animal use privileges, which should include additional ACUC recommendations such as extended oversight, must be made by a voting member of the ACUC. The reinstatement motion must include the time at which the reinstatement takes effect. The motion should be read to the ACUC 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 Animal Care and Use Committees (ACUCs) with the responsibility and authority to:

- 1. 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 ACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the ACUC 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.
- 2. 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.
- 3. 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:

- 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 ACUC suspends an activity involving animals, the Institutional Official, in consultation with the ACUC, 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 ACUC 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 ACUC approval. If the ACUC 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 ACUC 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 ACUC 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 ACUC. AWAR sec. 2.31(c)(8); PHS Policy IV.C.8.

Further amplifying and clarifying the AWARs and PHS Policy are various federal and university guides and policies. These include:

- 1. 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 Guide is formally established as University research policy by Board of Regents Policy Document 4-3 [http://www.uwsa.edu/bor/policies/rpd/rpd4-3.htm].
- 2. A memo from the Chancellor of UW-Madison confirming the authority of attending veterinarians over all aspects of animal care and treatment, including the authority "to intercede in any activity involving the use of animals for research or teaching purposes which in their judgment jeopardizes animal welfare or compliance with federal or university policies."