Washington State University
Institutional Animal Care and Use Committee

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<th>Policy #27</th>
<th>“Procedure for Addressing Non-Compliance with IACUC Policies or Procedures”</th>
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<td>Approval Date: 9/25/2019 (Replacing Version 2/2018)</td>
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A. Background

Non-compliance, whether accidental or intentional, occurs when procedures not approved by the IACUC are applied to animals in research or teaching, when there are deviations from the IACUC approved Animal Subjects Approval Form, or there is a departure from IACUC approved policies. Non-compliance ranges from minor protocol deviations (e.g., failure to notify IACUC of new personnel, minor changes in drug administration or sampling frequency, etc.) to significant. A significant deficiency is defined as one that is or may be a threat to animal health or safety. (e.g., unapproved animal procedures that result in animal death or disease, failure to provide post-operative analgesics, failure to follow safety procedures, etc.). The IACUC is responsible identifying non-compliance issues and ensuring appropriate corrective actions are in place to prevent reoccurrences.

B. Applicability

The policy applies to situations under the IACUC’s purview where a suspected non-compliance with Federal and WSU animal use policies is reported. Anyone can submit a report or identify a concern. Principal Investigators (PIs) are responsible for actions of those who work under their supervision. IACUC purview includes any activity associated with animal care and use program.
C. Procedure

Following the report, a preliminary inquiry will be initiated by Office of Research Assurances (ORA) Animal Welfare Program (AWP), Office of Campus Veterinarian (OCV), and/or IACUC. The inquiry may include a routine animal facility inspection, interviews of the Principal investigator (PI), students or staff, identification of funding sources or other resources appropriate to the problem.

In the event that there is an urgent safety or welfare concern identified in the preliminary inquiry, then the Attending Veterinarian or the Attending Veterinarian’s designee will expeditiously assess the concern. The Attending Veterinarian has the authority delegated by the Institutional Official (IO) & the IACUC to assess the animal, treat the animal, remove it from the experiment, institute appropriate measures to relieve pain or distress, or perform euthanasia if necessary.

The findings of the preliminary inquiry will be discussed with the PI and the PI’s response will be considered. The results of the preliminary inquiry and the PI’s response will be reported to the IACUC chair, ORA Director, AWP Assistant Director and Attending Veterinarian.

Based on Office of Laboratory Animal Welfare (OLAW) guidance and information, examples of reportable situations include, but are not limited to:

- conduct of animal-related activities beyond the expiration date established by the IACUC;
- failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
- failure to maintain appropriate animal-related records (e.g., identification, medical, surgical, husbandry);
• conduct of animal-related activities without appropriate IACUC review and approval;
• failure to adhere to IACUC-approved protocols;
• failure to report unanticipated adverse events to IACUC or OCV;
• participation in animal-related activities by individuals who are not listed on the approved protocol and have not been determined by the IACUC to be appropriately qualified and trained;
• failure to monitor animals post-procedurally as necessary to ensure well-being;
• failure to ensure death of animals after euthanasia procedures;
• failure of animal care and use personnel to carry out veterinary treatments;
• IACUC suspension that results in the temporary or permanent interruption of an activity due to noncompliance;
• Conditions that jeopardize the health or well-being of animals.

D. Actions

Follow up on reports of non-compliance:

1) Representatives of the following areas IACUC, OCV, ORA/AWP and if necessary the PI will review the results of preliminary inquiry and determine if there is a non-compliance issue. The PI will be notified whether noncompliance was established or not.

   a) If a determined non-compliance is associated with human safety or animal welfare concerns, a plan to correct the concerns will be developed and implemented if not already done so.

2) If significant non-compliance is identified, a letter of variation will be sent from the IACUC Chair, ORA Director or AWP Assistant Director to the PI. The letter should explain the basis of the non-compliance finding and required corrective actions. Depending on circumstances, the Departmental Chair or Director, the Associate Dean of Research (or
equivalent), Dean, Vice Chancellor of Research and the Institutional Official (IO) may also be included. Required corrective actions may include any or all of the following:

a) Mandating training aimed at preventing future incidents
b) Amending animal care and use protocols or standard operating procedures for IACUC approval
c) Enhanced monitoring of procedures and records by the IACUC or OCV including required procedural observations which may incur a service cost
d) Requiring the PI to provide a written response addressing the non-compliance to the satisfaction of the IACUC and/or to appear before the IACUC
e) Increased frequency of post-approval monitoring with updates provided to the IACUC at monthly meetings
f) Increased frequency of de novo protocol review (i.e. annually vs. every 3 years)
g) Protocol knowledge assessment (e.g. written or verbal test) of applicable personnel
h) Other actions such as those in response to animal welfare

3) If the non-compliance requires reporting to federal agencies (OLAW and/or USDA) or other funding sources, a report of the details, circumstances and correction of the non-compliance will be made by the Attending Veterinarian, IACUC Chair, ORA Director or AWP Assistant Director. Written reports to federal agencies and/or funding sources will be sent by the IO and copied to the PI. Depending on circumstances, the Department Chair, Dean, Associate Dean of Research (or equivalent) and/or Vice-Chancellor for Research may also be copied.

4) Results of the inquiry, subsequent reviews and required corrections will be communicated to the IACUC during convened meetings. The IACUC may choose to proceed with further review and further actions.
5) Repeated non-compliance is reviewed as described above and handled on a case-by-case basis. Repeated non-compliance may result in additional corrective actions and further actions, thereby jeopardizing ongoing animal activities.

When animal welfare incidents fall outside of the scope of this policy, then the review, determination and corrective actions fall to the discretion of the University Administration. The University Administration (generally the IO) may require further review, corrective actions, sanctions or suspensions but cannot approve an activity within the WSU Animal Care and Use Program that has not been approved by the IACUC.

E. Further Actions

1) In the event that further actions are required, the IACUC will decide on additional action at a convened meeting. This may involve requesting a more formal investigation.
   a) If no formal investigation is requested, the IACUC may proceed with corrective actions/sanctions as described in section D2 above or section F below.
   b) If a formal investigation is requested, in accordance with USDA Animal Welfare Act Regulations §2.31,(c),(4), a subcommittee of IACUC members and experts will be appointed to conduct the review.
      i) IACUC members and experts (e.g. ORA Director, AWP Assistant Director, etc.) appointed by the IACUC Chair can participate in the investigation.
      ii) The investigating team will provide the results of the investigation to the IACUC.
      iii) IACUC will determine a response appropriate to the non-compliance, which may include items listed in section D2 above or section F below.

F. At the completion of the IACUC investigation, results will be reported to the PI and the Vice President for Research (the WSU IO). In addition, the IACUC may choose to report the results to the PI’s Department Chair, School Director, Associate Dean of
Sanctions may be proposed by the IACUC following investigation of alleged noncompliance or following semi-annual site visits or any other observations of serious non-compliance. Sanction recommendations must be supported by a majority vote of a properly convened meeting of the IACUC prior to forwarding to the IO or the PI’s supervisor. Sanctions may include any one, or more, of the following:

- Counseling
- Issuing additional letters of reprimand
- Suspending an animal care and use protocol or standard operating procedure
- Temporary or permanent revocation of privileges to work with animals
- Temporary or permanent suspension of activities using animals
- Other actions such as those in response to animal welfare
- IO and Provost can impose sanctions (such as employment-related sanctions) beyond the IACUC’s authority.

IACUC decisions can be appealed in writing or in person at a convened meeting. The sanctions will remain in place until modified by a majority vote and a properly convened meeting.