Standard Operating Procedure for Non-Compliance with IACUC Policies or Procedures

Non-compliance with WSU IACUC policies, whether accidental or intentional, occurs when procedures not approved by the IACUC are applied to animals in research or teaching, or when PIs assurance on animal work is not followed. Non-compliance ranges from minor issues (failure to notify IACUC of new personnel, minor changes in experimental or teaching protocols, etc.) to major issues (unapproved animal procedures that result in animal death or disease, failure to provide for animal welfare, etc.).

I. A suspected non-compliance with WSU animal use policies is reported.

II. A preliminary inquiry is initiated by ORA/OCV/IACUC, which may include a routine animal facility inspection, interviews of the PI or research staff, or other responses appropriate to the problem.

III. The findings of the preliminary inquiry are discussed with PI and the PI's response is considered. The results of the preliminary inquiry are reported to the IACUC chair, and Office of Research Assurances (ORA) and the Office of the Campus Veterinarian (OCV).

IV. Based on OLAW guidance and information, non-compliance is classified as:

A. **No non-compliance**, requiring no further actions.

B. **Minor non-compliance**, with no adverse effect on animal welfare.
   a. If the non-compliance requires reporting to federal agencies (OLAW and/or USDA), a report of the details and circumstances of the non-compliance is made and the report is recorded in the database.
   b. The Institutional Official (IO) is informed of the non-compliance.
   c. A letter of variation is sent to the PI and copied to the database. The letter explains the basis of the non-compliance finding and suggests possible corrections.
   d. PAR personnel monitor the activities and verify that the corrections are implemented. If corrections are implemented in a satisfactory and timely manner, the non-compliance is considered resolved and no further actions are required. If the corrections are not implemented in a satisfactory or timely manner, the non-compliance returns to step II above or to step V below depending on the circumstances.

C. **Significant non-compliance**, with likely adverse effects on animal welfare.
   a. If non-compliance requires reporting to federal agencies (OLAW and/or USDA), the details and circumstances of the non-compliance are duly reported and the report is recorded in the database.
   b. The IO is informed of the non-compliance.
   c. The PI is contacted and the basis of the non-compliance finding is explained. Representatives of the IACUC, OCV, ORA, and the PI meet to explain the basis of the non-compliance finding and to develop a plan to correct the animal welfare situation as soon as possible. If a suitable plan cannot be developed or if continued non-compliance appears likely, the non-compliance moves to step V below.
d. On a case-by-case basis, representatives of the IACUC, OCV, and the ORA may require additional responses appropriate to the situation, which may include counseling, issuing letters of reprimand, mandating specific training intended to prevent future non-compliance, monitoring of on-going activities by IACUC or IACUC-appointed individuals, or taking the response to step V. below.

V. Animals are removed from non-compliant protocol to holding protocol. IACUC is convened to decide whether to authorize investigation.

   A. No investigation is authorized, and no further actions are required, and the non-compliance is considered resolved.
   
   B. An investigation is authorized, in accordance with PHS Policy IV, C, 6 & AWAR §2.31,d,6.
      
      a. IACUC members and experts appointed by IACUC can participate in the investigation.
      
      b. The investigating team provides the results of the investigation to IACUC.
      
      c. IACUC recommends a response appropriate to the non-compliance, which may include counseling, issuing letters of reprimand, mandating specific training intended to prevent future non-compliance, monitoring of on-going activities by IACUC or IACUC-appointed individuals, temporary or permanent suspension of animal-use privileges, and / or institutional sanctions via the WSU IO.

   C. At the completion of the IACUC investigation, results will be reported to the Principal Investigator (PI), the IACUC chair and vice-chair, the Director of the Office of Research Assurances, the Director of the Office of Campus Veterinarian, 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 and School Director and/or College Dean.

Note: IACUC has no authority to mandate institutional sanctions against any individual. However, IACUC can recommend the use of administrative sanctions to the IO.

**Institutional sanctions:**

Sanction recommendations may be proposed by the IACUC following investigation of alleged non-compliance 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.

**Suspensions:**

IACUC is empowered to suspend authorization for animal use in a project if it finds violation of University policy, PHS Policy, the Guide, Assurance, or Animal Welfare Regulations. Suspension may occur only after the review of the matter at a properly convened meeting of the IACUC. IACUC must consult with the IO regarding the reason(s) for suspension. The IO may take corrective action and must report the circumstances surrounding the suspension to OLAW, and for protocols involving covered species, to USDA.

WSU IACUC Approved 2.23.11