1.6.3 Noncompliance and Suspension of Animal Activities

A. Purpose/Scope
This document describes the process for reviewing allegations of noncompliance with federal regulations relating to the programs for animal care and use at this institution.

B. Definitions
- Assured Institution – an institution that has applied to the Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health (NIH) with documentation of assurance of institutional compliance with Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) and has received subsequent approval.
- Animal Activity – use of vertebrate animals for teaching, research, surgery, breeding, holding or demonstration
- IACUC – Institutional Animal Care & Use Committee
- Principal Investigator (PI) - the person who has accepted responsibility for directing the conduct of animal activity as described in an approved IACUC protocol or amendment and who has signed the assurance statement obliging him/her to conduct this activity in accordance with all animal welfare guidelines and regulations.
- University Research Compliance Officer (RCO) - acts to oversee and ensure research compliance with regulations applicable to the use of human and animal subjects, biosafety and pre-award grants administration. In this capacity, the RCO ensures that all research conducted at the University adheres to the applicable federal and state regulations.
- Research Compliance Office (RCO) – staff member(s)
- IACUC Office – staff member(s)
- Institutional Official (IO) - Senior Vice President for Research
- Quorum - one more than half of the number of voting members of the IACUC
- TNPRC- Tulane National Primate Research Center
- DVM- Division of Veterinary Medicine (TNPRC)
- DCM- Department of Comparative Medicine
- AV- Attending Veterinarian

C. References
- Animal and Plant Health Inspection Services (APHIS), United States Department of Agriculture (USDA), 9 CFR, Subchapter A-Animal Welfare
- National Research Council, Guide for the Care and Use of Laboratory Animals (Guide), National Academy Press, Washington DC, 2011
- Reporting Animal Concerns- - Research Compliance Office policy
D. **Background**

Since Tulane University is a PHS supported and assured institution, its facilities must adhere to the *PHS Policy on Humane Care and Use of Laboratory Animals (PHS policy)*. This policy uses the *Guide for the Care and Use of Laboratory Animals (Guide)* and regulations (9 CFR, Subchapter A) issued by the USDA as the basis for monitoring approved animal activity for compliance with all applicable guidelines and regulations.

E. **Procedures**

1. An animal care and use program comprises the IACUC program, the DCM program, the DVM program and PIs and staff. Concerns or complaints can be made about any aspect of the animal care and use program and may be reported to one of several individuals and/or departments. IACUC members are responsible for referring any concern received to the IACUC chair or the RCO. If the chair is notified he or she contacts the RCO with the initial report. If the RCO receives a complaint he or she notifies the IACUC chair of the issue. The RCO is responsible for assigning a case number and uploading all relevant documents to the research compliance shared folder. The IACUC chair is responsible for oversight of all research compliance issues for the animal care program except allegations made in reference to the IACUC.

2. The RCO will notify the parties involved that an investigation is underway.

3. If animal health or well-being is at risk the IACUC chair will contact the AV immediately. The AV will investigate immediately and report findings and possible interventions to the IACUC chair. If appropriate, the PI will be asked to temporarily stop the work and the animals involved will be removed from the study and given routine clinical care until the investigation is completed. If the PI does not agree to halt the study, an emergency meeting of the IACUC will be convened and the committee will review the proposal for suspension of the research. (See 10 a-f below).

4. The RCO is responsible for providing reports to the IO.

5. If needed, a subcommittee composed of committee members (must include a veterinarian and a scientific member) will be appointed by the Chair to assist with the investigation and resolution of the incident. There may be reported concerns that can be presented to the IACUC without the use of a subcommittee.

6. The subcommittee may meet with the PI involved and/or review relevant documentation. The subcommittee will make recommendations to resolve the incident and to prevent its recurrence. The report will be presented at an IACUC meeting for review and disposition.

7. Once the IACUC has agreed on a disposition for the incident the RCO will notify the individual(s) involved and inform appropriate administrators of the decision.

8. The RCO or the IACUC chair can make the initial report to OLAW by phone. Follow-up or final reports to USDA or OLAW will be drafted by the RCO, reviewed by the IACUC chair and reviewed and sent by the IO.

9. The RCO is responsible for reporting the incidence to funding agencies if necessary.

10. If the committee decides to suspend a research project, the following procedures must be followed:

   a. The IACUC is empowered to suspend a project if it finds noncompliance with the PHS Policy, *Guide*, Assurance, or violations of the Animal Welfare Act Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and with a majority of the quorum present supporting the decision.

   b. Once the IACUC suspends an animal activity, the IO, in consultation with the IACUC and the RCO, will review the reasons for suspension and take appropriate corrective action.
c. Either the chair or the RCO will make an initial report of suspension to OLAW. Final reports for suspension are sent by the RCO through the IO. If the suspension involves a species covered under the Animal Welfare Act, the RCO will submit a report to the USDA.

d. The PI or responsible party whose animal activity has been suspended will be notified in writing of the decision and any description and timetable for corrective action.

e. The DVM or DCM will be notified, and all scheduling and support of activities beyond routine husbandry and clinical care of the animals will cease until further notice.

f. If an animal activity is authorized to resume after suspension, the IACUC office will notify the IO, the DVM or DCM, and the investigator or responsible party regarding the change in status.

Approved by the IACUC

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