Subject: Principal Investigator Responsibilities

BACKGROUND

This Standard Operating Procedure (SOP) describes the role of the Principal Investigator designated on an Institutional Animal Care and Use Committee (IACUC) protocol. A Principal Investigator (PI) must have the experience, professional qualifications, and access to the research facilities and resources necessary to ensure the proper care and use of vertebrate animals in research and/or teaching. For purposes of the submission of all research proposals involving vertebrate animals at Wayne State University, the Institutional Animal Care and Use Committee recognizes only one individual as the principal investigator. If an individual who is not a WSU faculty member or veterinarian requests to serve as a PI, s/he must have a Faculty Advisor who is a WSU faculty member listed on the protocol. All other investigators on the protocol are considered co-investigators or key personnel.

Scope

This Standard Operating Procedure applies to all persons who accept the responsibility as Principal Investigator to conduct research using vertebrate animals at Wayne State University or any of its affiliate institutions. This includes faculty, staff, and students at the institution.

General Responsibilities

The Principal Investigator must:

- Comply with the Animal Welfare Act Regulations (AWRs [CFR 1985]), the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy [PHS 1996]), U.S. Department of Agriculture, and other applicable federal, state, and local laws, regulations, and policies. The Guide for the Care and Use of Laboratory Animals (the Guide, NRC 2011) outlines all the PHS requirements followed by the IACUC.

  The Guide, Ethics and Animal Use

  “The decision to use animals in research requires critical thought, judgment, and analysis. Using animals in research is a privilege granted by society to the research community with the expectation that such use will provide either significant new knowledge or lead to improvement in human and/or animal well-being (McCarthy 1999; Perry 2007). It is a trust that mandates responsible and humane care and use of these animals. The Guide endorses the responsibilities of investigators as stated in the U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.” (p. 4)

- Work closely with the WSU veterinarians for animal care issues, especially if complications arise per the Guide, Emergency Care (p.114)
  - In the case of a pressing health problem, if the responsible person (e.g., investigator) is not available or if the investigator and Division of Laboratory Animal Resources (DLAR) veterinary staff cannot reach consensus on treatment, the DLAR veterinarian assessing the case has the authority to treat the animal, remove it from the experiment, institute appropriate measures to relieve severe pain or distress, or perform euthanasia if necessary.

- Conduct the study in accordance with the written protocol approved by WSU IACUC.

- Comply with all IACUC policies, procedures, decisions, conditions and requirements.

- Maintain oversight of the research protocols and research staff.
• Ensure that all members of the research team are adequately trained, both initially and throughout the course of the study. This includes students and other trainees, visiting scientists, and volunteers who are directly involved with the project.

• Maintain complete records and documentation appropriate to the type of research.

• Participate in the Post Approval Monitoring (PAM) program as requested by the Office of Research Integrity.

• Implement appropriate safety practices and procedures while working with hazardous agents or materials for lab staff and DLAR staff.

**Official IACUC Procedures**

**The Principal Investigator must:**

• Submit a protocol and the associated grant, if applicable, for all research and/or teaching involving vertebrate animals to the Committee for review. Research and/or teaching cannot begin until all requested changes or clarifications are described in the revised protocol, all paperwork/approvals from the Office of Environmental Health and Safety (OEHS) have been received by the IACUC Office, and all training has been completed by the PI and laboratory personnel. After all the requirements have been met, the IACUC Office will generate a letter of approval; the PI cannot begin the project until he/she receives the letter.

• Submit revised protocols within 60 days of receipt of IACUC correspondence; unrevised protocols will be withdrawn after this time period has elapsed, and a new application must be submitted to the IACUC.

• Submit an amendment request for all proposed protocol modifications before any changes are initiated (see the Amendment Policy Review of Significant Changes to Approved Protocols).

• Complete the appropriate paperwork for annual review. Submit a Continuing Review every year (i.e. years 1 and 2 post-approval) to receive continued protocol approval.

• Submit a new protocol for work that will continue beyond the three-year approval period.