Policy # SI-05-2011

Policy Title: Principal Investigator Eligibility and Responsibilities When Developing/Implementing Protocols

Policy: The Guide for the Care and Use of Laboratory Animals, 8th Edition states that principal investigators (PIs) must have precise knowledge of both the objectives of the study and the proposed model. Protocol development and implementation is an undertaking that requires a Principal Investigator (PI) to consider and follow a variety of regulations, guidelines and policies. In order to define the eligibility for PIs, and to provide individuals with pertinent details pursuant to their responsibilities as Principal Investigators on animal research protocols, the following checklist has been developed:

As the PI you must:

- Possess the technical and/or subject matter expertise pertinent to the protocol and activities described therein.

- Have demonstrated responsibility and accountability.

- Demonstrate that the use of all animals proposed is not unnecessarily duplicative of research already performed (by yourself or others).

- For all category D and E procedures, review two or more pertinent scientific databases and/or pertinent literature sources, to ensure a lack of valid alternative to any procedures described that may cause more than momentary pain and distress, (whether relieved or not).

- Consult with a member of ACS veterinary staff when pain and distress is beyond the level anticipated in the protocol description, or when interventional control is not possible.

- Review the qualifications of all personnel listed in Appendix C, and determine that they:
  - Are authorized to conduct procedures involving animals relevant to your project;
  - Have completed the required IACUC training course;
  - Have completed all required EHS training;
  - Have received additional training, as appropriate, in:
    - The biology, handling, and care of the species used, and are competent in executing procedures
    - Aseptic surgical techniques and methods
    - The concept, availability, and use of research or teaching methods that limit use of animals or minimize distress
    - The proper use of anesthetics, analgesics, and tranquilizers
    - Procedures for reporting animal concerns
• All required training that will minimize the risk of exposure to animal research related physical, chemical, biological, or environmental hazards inherent in the project

• Ensure that all individuals are participating in the University’s Occupational Health and Safety Program for animal handlers.

• Execute procedures as described in the protocol, without unauthorized deviations or substitutions or drugs or procedures.

• Obtain approval from the IACUC before initiating modifications to the protocol. If you are unsure what constitutes a modification, contact the IACUC office.

• Notify the IACUC immediately regarding any unexpected project results that deleteriously impact animals.

• Notify the veterinary staff immediately if there are any issues or occurrences of unanticipated pain, distress, mortality, or morbidity in the research animals.

• Make copies of the approved protocol, and any subsequent modifications, available to all laboratory personnel.

• Maintain current drug licenses and proper storage and documentation procedures for any controlled substances you use in a project.

• On a monthly basis, monitor drugs used in the laboratory and discard any that are expired following proper disposal procedures.

• Maintain complete, up-to-date, and accessible records for animal health and animal procedures used in a project.

• Comply with policies set forth by the Animal Welfare Act and Public Health Service Policy. Accordingly, you must comply with the standards of animal care and use set forth by the *Guide for the Care and Use of Laboratory Animals*, or the *Guide for the Care and use of Agricultural Animals in Research and Teaching*; as applicable to the species and procedures you are utilizing.