Title: SOP - Education and Training Strategies in the Care and Use of Animals for IACUC Members and the Institutional Official

Approval:

Attending Veterinarian  Date: 08/19/16

IACUC Chair  Date: 08/18/16

1. **Purpose**

   1.1 Florida International University grants the privilege of using animals in research with the understanding and expectation that such research is conducted according to the highest ethical and legal standards by highly trained personnel that are involved in animal care, treatment or use.

   1.2 Personnel qualifications are the subject to three Congressional Acts: the Health Research Extension Act (Public Law 99-158), the Food Security Act (Public Law 99-198), and the Animal Welfare Act (AWA) [7 U.S.C. 2131-2156].

   1.3 The AWA details requirements for the care and use of animals in research, testing and education. Specifically, Subpart C, Section 2.32, Personnel Qualification, requires that:

      1.3.1 It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel.

      1.3.2 Training and instruction shall be made available, and qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility's responsibilities under this section.
1.3.3 USDA Animal and Plant Health Inspection Service (APHIS) Animal Care Policy #15, I.O and IACUC Membership, (2011 revision) states: “IACUC members must be qualified to assess the research facility’s animal program, facilities and procedures. The research facility is responsible for ensuring their qualification, and this responsibility is filled in part through the provision of training and instruction.” For example, IACUC members should be trained in understanding the Animal Welfare Act, protocol review, and facility inspections. As a result of this policy revision, USDA’s veterinary medical officers (VMOs) are specifically inquiring institutions during the annual inspections for provided training to the IACUC members.

1.4 The basic principles governing animal research are found also in the United States (U.S.) Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, and include the following imperative (paragraph h) related with the training:

1.4.1 Personnel need to have appropriate qualifications, training, and experience when conducting procedures on animals. Opportunities for hands-on training need to be provided as needed.

1.5 Federal laws and regulations require Florida International University to oversee and evaluate the program, facilities, and procedures for using animals in research, teaching, and/or testing activities. These responsibilities are specifically charged to the Institutional Official (IO) and the Institutional Animal Care and Use Committee (IACUC). The individuals tasked with these responsibilities need to possess the requisite knowledge or experience to fulfill their responsibilities effectively.

2. Responsibility

2.1 Institutional Official, Attending Veterinarian, IACUC Members, Principal Investigators

3. Definitions

3.1 AAALAC: Association for Assessment and Accreditation of Laboratory Animal Care International;

3.2 AALAS: American Association for Laboratory Animal Science;

3.3 Animal research refers to any use of laboratory animals in research, testing, or training;

3.4 Animal is defined as any live vertebrate animal used or intended for use in research, research training, experimentation, or biological testing, or for a related purpose (see PHS Policy on Humane Care and Use of Animals, Sec. III). For the purpose of compliance with the Animal Welfare Act Regulations an animal is defined as any live or dead cat or dog, non-human primate, guinea pig, hamster, rabbit, or any other warm-blooded animal, which is being used, or is intended for use in research, teaching, testing, or experimentation.
term excludes birds, rats of the genus Rattus and mice of the genus Mus bred for use in
research, and horses not used for research purposes and other farm animals, such as, but
not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or
poultry used or intended for use in improving animal nutrition, breeding, management, or
production efficiency, or for improving the quality of food or fiber;

3.5 AV: Attending Veterinarian;

3.6 AWA: Animal Welfare Act;

3.7 Institutional Official: the individual responsible for all research activities conducted at
Florida International University, and serves as the Institutional Official (IO). The IO is the
responsible official for correspondence related to animal research with AAALAC and USDA.
FIU operates one IACUC;

3.8 NRC Guide: Guide for the Care and Use of Laboratory Animals;

3.9 OLAW: Office of Laboratory Animal Welfare;

3.10 PHS: US Public Health Service;

3.11 PRIM&R: Public Responsibility in Medicine and Research;

3.12 SCAW: Scientists Center for Animal Welfare;

3.13 IACUC: Institutional Animal Care and Use Committee;

3.14 USDA: United States Department of Agriculture;

3.15 VMO: Veterinary Medical Officers (USDA)

4. Guidelines

4.1 IACUC members:

4.1.1 Initial Training of Prospective Committee Members:

4.1.1.1 During the recruitment process, the “recruiter” should discuss IACUC
responsibilities including the time commitment for attending meetings,
reviewing the program and protocols, and inspecting facilities.

4.1.1.2 An opportunity to attend IACUC meetings can help prospective members with
their decision-making process.

4.1.1.3 During these interactions, the IACUC has an opportunity to educate the
potential members about the role of the committee, and to generate interest in
serving as committee members.
4.1.2 Orientation of New IACUC Members

4.1.2.1 Initial training of IACUC members can begin by attending Animal Facility Orientation. The goal of orientation should be to provide an overview and the necessary resource documents to allow new members to be effective members within their first few months on the committee.

4.1.2.2 The new members would be provided an overview of the expectations for new members, which would include the roles of the following key members of the animal care and use program: the scientists, the Attending Veterinarian (AV), IACUC Chair, the Institutional Official (IO), the animal husbandry and veterinary technical staff, and the IACUC itself.

4.1.2.3 New members are required to successfully complete the CITI Essentials for FIU IACUC Members Course, which covers the following topics:

4.1.2.3.1 Introduction to Essentials for IACUC Members
4.1.2.3.2 Responsibilities of the IACUC and IACUC Members
4.1.2.3.3 The Members of the IACUC
4.1.2.3.4 The IACUC, the CEO, and the IO
4.1.2.3.5 Authority of the IACUC
4.1.2.3.6 Conducting IACUC Business–The Quorum
4.1.2.3.7 Procedures for Reviewing Protocol Forms
4.1.2.3.8 Outcomes of Animal Protocol Reviews
4.1.2.3.9 The Types of Protocol Reviews
4.1.2.3.10 Documenting IACUC Actions
4.1.2.3.11 The IACUC Semi-Annual Evaluation
4.1.2.3.12 Performing the Facility Inspection and the Program Review
4.1.2.3.13 Identifying, Documenting, and Correcting Deficiencies
4.1.2.3.14 Investigating Allegations of Improper Animal Care or Use.
4.1.2.3.15 Maintaining the Public Trust
4.1.2.4 New members will also receive hands-on specialized training regarding the mechanisms for reviewing protocols within the TOPAZ Online Electronic Protocol Submission System.

4.1.2.5 Resource documents:

4.1.2.5.1 IACUC members must have the following resource documents that can be accessed online or can be provided upon request as electronic or hard copies:

4.1.2.5.1.1 The Animal Welfare Act of 1966 (P.L. 89-544) and subsequent amendments, as promulgated in USDA regulations 9 CFR Chapter 1, Subchapter A, Animal Welfare. Parts 1, 2, and 3. USDA-APHIS-AC Unit 84, 4700 River Rd., Riverdale, MD 20737, 301/734-7833. (http://www.nal.usda.gov/awic/legislat/usdaLeg1.htm)


4.1.2.5.1.4 Guidelines of the AVMA on Euthanasia, JAVMA 2007 (https://www.avma.org/KB/Policies/Documents/euthanasia.pdf)

4.1.2.6 Recommended resource documents that can be accessed as needed:


4.1.2.6.2 AAALAC International Position Statements (http://www.aaalac.org/accreditation/positionstatements.cfm)

4.1.2.6.3 American College of Laboratory Animal Care – Position Statements (http://www.aclam.org/education/guidelines/position.html)


4.1.3 Continuing Education Resources for IACUC Members: the following resources can be used alone or in any combination as needed:

4.1.3.1 Annual Review of IACUC and ACF SOP’s. The periodic review of institutional SOP’s pertaining to the animal care and use program is essential as new animal species, models, and/or procedures are introduced.

4.1.3.2 Resources to attend workshops and conferences: Training programs such as IACUC 101 and the PRIM&R and SCAW conferences as well as other external training programs serve as excellent training activities.

4.1.3.3 The IACUC meeting itself: The meeting can be used to introduce and train a prospective or new member by partnering that person with a more experienced member who serves as a mentor.

4.1.3.4 Distribution of relevant articles, newsletters, and information before or at the meeting.

4.1.3.5 Consultation and ongoing one-on-one guidance to individual members by the chairperson, AV, and IO to respond to specific questions and to provide clarification of issues as they arise.

4.1.3.6 Participation in AAALAC International site visit is an excellent opportunity for the continuing education of IACUC members.

4.1.3.7 External Training Programs that can be provided to IACUC members are available through state and regional associations and federal agencies as well as major biomedical research associations and organizations:

4.1.3.7.1 American Association for Laboratory Animal Science (AALAS). The AALAS National Meeting offers a focus on IACUC training within the session track “Animal Welfare, Regulatory Compliance, and Public Education.” IACUC topics are addressed in poster sessions, seminars, special topic.
lectures, workshops, and roundtable discussions. Information is available at www.iacuc.org

4.1.3.7.2 Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International). Topical education services are provided by AAALAC International in the form of in-house training sessions. This program is intended to help institutions “proactively manage animal care and use issues in ways that meet AAALAC International standards.” The program consists of several modules, all under the heading of “AAALAC International’s Expectations for Animal Care and Use Committees” and presented over a period of 6.5 hours. Information is available at www.aaalac.org

4.1.3.7.3 Public Responsibility in Medicine and Research (PRIM&R). PRIM&R is a national organization dedicated to creating, implementing, and advancing the highest ethical standards in the conduct of research. On an annual basis, PRIM&R presents a day of pre-conference programs followed by a 2-day annual IACUC conference. Information is available at www.primr.org

4.1.3.7.4 Scientists Center for Animal Welfare (SCAW1). SCAW advances the responsible use of research animals in a variety of venues including annual conferences, workshops, and publications, all of which cover topics of interest to IACUCs. In addition, SCAW offers IACUC-Advanced for more seasoned IACUC members. This 1-day workshop facilitates group discussions about specific, complex topics relevant to IACUC functions and best practices. Information is available at www.scaw.com

4.1.3.7.5 Animal Welfare Information Center (AWIC). A 1 and 1/2-day workshop, “Meeting the Information Requirements of the Animal Welfare Act,” is offered several times throughout the year by AWIC via the USDA National Agricultural Library (NAL). The workshop focuses on the AWA, the concept of the 3Rs (refinement, replacement, reduction; Russell and Burch 1959), the regulatory requirements for conducting animal alternatives searches, literature resource services including NAL AWIC, and instruction for seeking alternatives information using various literature databases and networks.

4.1.3.7.6 IACUC 101 series. Cosponsored by OLAW and PHS assured institutions, state biomedical research associations, and/or national organizations, the IACUC 101 series consists of didactic and interactive training programs designed to provide information on the role and responsibilities of IACUCs, including an understanding of federal policies
and regulations governing laboratory animal welfare. The 1- or 2-day programs are offered across the country approximately six times a year. The course features a didactic comprehensive overview of laws, regulations, and policies supplemented with examples and approaches for successful and effective implementation and administration, followed by an opportunity to participate in deliberative and challenging mock IACUC sessions. The IACUC 101 program focuses on the basics, while the supplemental IACUC 101 PLUS, 201, and 201 PLUS programs focus on processes and include several highly interactive breakout sessions. Information is available at http://grants.nih.gov/grants/olaw/iacuc101s.htm

4.2 Institutional Official (IO): at FIU, the IO is aware of the regulations, recognizes and supports the key players in the program and is familiar with the regulatory documents identified in Paragraph 4.1.2.4.

4.2.1 Important regulatory information related with the animal care and use program that help to guide the IO is contained in the following resources:

4.2.1.1 PHS Policy on Humane Care and Use of Laboratory Animals: To receive funds from any PHS agency (such as the NIH) the institution must be in compliance with the PHS Policy on Humane Care and Use of Laboratory Animals.

4.2.1.2 NRC Guide: The Introduction and Chapter 1 of the NRC Guide provide an overview of expectations of a program. An institution accredited by AAALAC International must be in compliance with the NRC Guide.

4.2.1.3 The two-page “Quick Reference to the Responsibilities and Functions of the Institutional Official (IO) for Research Facilities under the Animal Welfare Act,” available at www.nal.usda.gov/awic/legislat/awabrief.htm is another good resource.

5. References

5.1 The Guide for the Care and Use of Laboratory Animals 8th Edition (NRC 2011)

5.2 M. E. Greene, M. E. Pitts, and M. L. James: Training Strategies for Institutional Animal Care and Use Committee (IACUC) Members and the Institutional Official (IO); ILAR Journal Volume 48, Number 2 2007.

6. Revision

6.1 Revision 02: 2016 IACUC Review