Valdosta State University Institutional Animal Care & Use Committee

Standard Operating Procedure Number 002

DEFINITIONS AND REFERENCES UTILIZED BY THE IACUC

PURPOSE: The purpose of this Standard Operating Procedure (SOP) is to define the terms utilized by the Institutional Animal Care and Use Committee (IACUC) in implementing its other Standard Operating Procedures and to identify references accepted and utilized by the IACUC in carrying out its responsibilities.

DEFINITIONS:

<u>Activity</u> – Any element of research, testing, or teaching procedures that involves the care and/or use of animals. IACUC approval must be obtained prior to any activity involving the use of animals. Excluded under this definition are activities involving only observation that do not interfere or interact with the animals. For example, using feeders or providing animals with shelter would not be excluded.

<u>Administrative Noncompliance</u> – Acts that do not directly impact the physical or psychological welfare of animals, including, but not limited to, such acts as failing to complete and submit reports and other paperwork in accordance with IACUC procedures and timelines, failing to follow administrative instructions given by the IACUC, the Attending Veterinarian, and/or the IACUC Administrator; and failing to adhere to other related guidelines and practices.

<u>Allegation</u> – Any written or oral statement or other indication of possible animal mistreatment and/or injurious or non-injurious noncompliance made to a University official.

<u>Animal</u> – Any live non-human vertebrate animal used or intended for use in research, training, experimentation, testing, propagation, or related purpose, with the exclusion of embryos, tissue, and other biological samples.

- For embryos, the point in development at which oviparous, ovoviviparous, and viviparous species become regulated animals is specified by the Animal Welfare Act (AWA) and the Office of Laboratory Animal Welfare (OLAW). Viviparous and ovoviviparous species become regulated at parturition from the maternal animal. Oviparous species become regulated when they hatch from the egg. For fish, the VSU IACUC has determined a similar stage in development as the "buttoned-up" stage (when the embryo has fully absorbed the yolk sac and must forage on its own).
- For tissues and other biological samples, only those that have been collected from a live animal by a Valdosta State University investigator are regulated.

<u>Animal Bite or Exposure</u> – Having one's skin pierced or abraded by animal teeth or claws, or by coming in contact with animal saliva or tissue on abraded skin, eyes, or mucus membranes or through needle stick after the needle has penetrated animal tissue.

<u>Animal Facility</u> – Any building, room, area, enclosure, or vehicle, including field stations and associated structures in which animals are housed for more than 12 hours that is assigned for confinement, transportation, maintenance, breeding, or experiments inclusive of surgical

manipulation. This also includes similar areas assigned for animal food preparation and storage. Animal areas containing free-living wild animals in their natural habitat are not included in this definition.

<u>Animal Use Area</u> – Any building room, area, enclosure, or other containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 12 hours.

<u>Animal Use Protocol (AUP)</u> – The application form required by the Institutional Animal Care & Use Committee (IACUC) for approval of proposed research, testing, or instruction utilizing vertebrate animals.

<u>Animal User</u> – Any Valdosta State University faculty, staff member, or student who is involved in an activity with animals. External researchers involved in an activity with animals on the VSU campus who agree to operate under the auspices of VSU IACUC are also included in this definition.

<u>APHIS</u> – Animal and Plant Health Inspection Service, U.S. Department of Agriculture.

<u>AUP</u> – Animal Use Protocol. The application form required by the Institutional Animal Care & Use Committee (IACUC) for approval of proposed research, testing, or instruction utilizing vertebrate animals.

<u>AVMA</u> – American Veterinary Medical Association. Provides euthanasia guidelines for various animal species.

<u>CDC</u> – Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (DHHS). Principal federal agency charged with protecting the health and safety of the public.

<u>DHHS</u> – U.S. Department of Health & Human Services.

<u>Euthanasia</u> – The humane destruction of an animal accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death.

<u>Field Study</u> – A study conducted on free-living wild animals in their natural habitat when there are no invasive procedures used and there are not procedures employed that harm or materially alter the behavior of the animals under study.

<u>Good Faith Allegation</u> – An allegation made with the honest belief that animal mistreatment and/or injurious or non-injurious noncompliance may have occurred. An allegation is not in good faith if it is made with reckless disregard for, or willful ignorance of, facts that would disprove the allegation.

<u>Husbandry</u> – activities including but not limited to feeding, watering, macroenvironment and microenvironment cleaning, breeding, health examination, and atmospheric conditions.

<u>IACUC</u> – Institutional Animal Care & Use Committee. An independent committee, required by the USDA Animal Welfare Regulations and the PHS Policy on Humane Care and Use of

Laboratory Animals, established by research facilities to review, require modifications to, and approve or disapprove an Animal Use Protocol (AUP).

<u>Informant</u> – The person who makes an allegation of animal mistreatment and/or injurious or non-injurious noncompliance.

<u>Injurious Noncompliance</u> – Conducting a painful, distressful, or invasive procedure on an animal without IACUC approval, or failure to follow procedures approved by the IACUC, resulting in increased risk of animal pain, distress, morbidity, or mortality.

<u>Institutional Official</u> – The individual at a research facility or institution who is authorized to legally commit on behalf of the research facility or institution that federal animal care and use regulations are being met and that appropriate resources are committed to the animal care and use program.

<u>Investigation</u> – The second step in addressing an allegation of animal mistreatment and/or injurious or non-injurious noncompliance. Undertaken when results of the preliminary review indicate that the allegation appears justified in order to determine if indeed such mistreatment and/or noncompliance has occurred and, if so, to recommend appropriate actions.

<u>Macroenvironment</u> – Space in which animal microenvironments are located.

<u>Macroenvironment Cleaning</u> – The sanitization of animal housing rooms, including washing walls, counter tops, sinks, floors, cage racks, and any other equipment located in the housing room.

<u>Microenvironment</u> – The physical environment that immediately surrounds the animal and is bounded by the primary enclosure or cage in which the animal resides.

<u>Microenvironment Cleaning</u> – The sanitization of animal housing, including cage washing, sterilization, and bedding changes.

<u>Mistreatment</u> – Abusive or wrongful physical or psychological treatment of an animal, including striking animals or otherwise inflicting physical pain or harm; taunting animals; not providing food for punitive reasons; and purposefully placing animals in an environment in which aggressive behavior against other animals or humans is encouraged.

<u>NIOSH</u> - National Institute for Occupational Safety and Health (NIOSH) is the federal agency responsible for conducting research and making recommendations for the prevention of work-related injury and illness. NIOSH is part of the CDC in DHHS.

<u>Noncompliance</u> – Failure of an animal user to follow applicable laws, regulations, policies, procedures, approved protocols, and/or directives of the IACUC or the Attending Veterinarian. Acts of noncompliance may be classified as injurious, non-injurious, or administrative.

<u>Non-Injurious Noncompliance</u> – Unapproved utilization of animals in research or teaching in such a way that the animals do not suffer pain or distress or experience morbidity or mortality; or failure to follow IACUC-approved procedures that impacts animals or the total animal population without concomitant increase in risk of animal pain, distress, morbidity, or mortality.

<u>OLAW</u> – Office of Laboratory Animal Welfare, Public Health Service (PHS), U.S. Department of Health & Human Services (DHHS). Provides guidance and interpretation of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, supports educational programs, and monitors compliance with the Policy by Assured institutions and PHS funding components to ensure the humane care and use of animals in PHS-supported research, testing, and training, thereby contributing to the quality of PHS-supported activities.

<u>Painful Procedure</u> – Any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a human being to which that procedure was applied (i.e., pain in excess of that caused by injections or other minor procedures).

<u>Paralytic Drug</u> – A drug that causes partial or complete loss of muscle contraction and which has no anesthetic or analgesic properties, so that the animal cannot move but is completely aware of its surroundings and can feel pain.

<u>Passive Observation</u> – Procedure in which the animal user does not come into contact with animal(s) and does not interfere with behavior patterns of animals (for example, their nests).

<u>PHS</u> – Public Health Service, U.S. Department of Health & Human Services.

<u>Preliminary Review</u> – The first step in addressing an allegation of animal mistreatment and/or injurious or non-injurious noncompliance. The purpose of the preliminary review is to ensure that frivolous or uninformed accusations are dismissed and that differentiation is made between willful animal mistreatment and/or noncompliance and carelessness or incompetence.

<u>Principal Investigator</u> – A faculty member or student who is responsible for proposing and implementing a protocol to conduct animal research or to utilize animals in testing or instruction.

Quorum – A majority of committee members.

<u>Respondent</u> – The person against whom an allegation of animal mistreatment and/or injurious or non-injurious noncompliance is directed or the person whose actions are the subject of a preliminary review and/or investigation.

<u>Research Facility</u> – Any school (except an elementary or secondary school), institution, organization, or person that uses or intends to use live animals in research, tests, or experiments, and that (1) purchases or transports live animals in commerce, or (2) receives funds under a grant, award, loan, or contract from a department, agency, or instrumentality of the United States for the purpose of carrying out research, tests, or experiments.

<u>Retaliation</u> – Any action taken by the institution or an employee of the institution that adversely affects the employment or other institutional status of the informant who has, in good faith, made an allegation of mistreatment and/or noncompliance or of any other person who has cooperated in good faith in the review and/or investigation of such allegation.

<u>Sanction</u> – Any penalty or coercive action taken by the IACUC to help ensure compliance with applicable regulations, policies, and procedures for the care and use of animals in research and instruction.

<u>Sanitize</u> – To make physically clean and to remove and destroy, to the maximum degree that is practical, agents injurious to health.

<u>University Official</u> – The individual who receives an allegation of animal mistreatment and/or injurious or non-injurious noncompliance. He/she may be a faculty member, department head, academic dean, the Attending Veterinarian, any IACUC member, or the IACUC Administrator.

<u>USDA</u> – U.S. Department of Agriculture.

<u>Zoonotic Diseases (Zoonoses)</u> – Diseases that are communicable from animals to humans under natural conditions.

REFERENCES:

<u>Regulatory Agencies</u>:

- U.S. Department of Agriculture <u>Animal and Plant Health Inspection Service (APHIS)</u> http://www.aphis.usda.gov/
- U.S. Department of Health & Human Services Public Health Service - National Institutes of Health <u>Office of Laboratory Animal Welfare (OLAW)</u> http://grants.nih.gov/grants/olaw/olaw.htm

Laws, Regulations, and Policies:

 <u>U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in</u> <u>Testing, Research, and Training</u> – http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples

• <u>Animal Welfare Act</u> (7 U.S.C. 2131 et. seq.) – http://www.aphis.usda.gov/animal_welfare/awa.shtml

- <u>Animal Welfare Regulations</u> Implementing regulations of the Animal Welfare Act (Code of Federal Regulations, Title 9, Chapter 1, Subchapter A, Parts 1, 2, and 3) http://www.aphis.usda.gov/animal_welfare/awr.shtml
- Health Research Extension Act of 1985, Public Law 99-158, November 20, 1985, "Animals in Research " – http://grants.nih.gov/grants/olaw/references/phspol.htm#HealthResearchExtensionActof1 985
- <u>NIH Revitalization Act of 1993</u>, Public Law 103-43, June 10, 1993, "Plan for Use of Animals in Research" http://grants.nih.gov/grants/olaw/pl103-43.pdf
- U.S. Public Health Service Policy on Humane Care and Use of Laboratory Animals -

http://grants.nih.gov/grants/olaw/references/phspol.htm#PublicHealthServicePolicyonHu maneCareandUseofLaboratory.

<u>Guidelines</u>:

- *Guide for the Care and Use of Laboratory Animal.* National Research Council (NRC). National Academy Press, Washington, DC, 2011. <u>Click here</u> to *download a PDF of the Guide.* Under copyright agreement, **individuals may download only a single copy for their personal use from this website**.
- <u>Guidelines for Ethical Conduct in the Care and Use of Animals</u> (American Psychological Association) http://www.apa.org/science/anguide.html
- <u>Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research</u>, 2003 –

 $http://grants.nih.gov/grants/olaw/National_Academies_Guidelines_for_Use_and_Care.p~df$

- <u>Recognition and Alleviation of Distress in Laboratory Animals</u>, 2008 http://grants.nih.gov/grants/olaw/NAS_distress_report.pdf
- <u>Guidelines for the Use of Fishes in Research</u>. The American Fisheries Society, the American Institute of Fisheries Research Biologists, and the American Society of Ichthyologists and Herpetologists, 2004 http://www.fisheries.org/afs/docs/policy_guidelines2004.pdf
- <u>Guidelines for Use of Live Amphibians and Reptiles in Field and Laboratory Research</u> (American Association of Ichthyologists and Herpetologists) – http://www.asih.org/files/hacc-final.pdf
- DeNardo, Dale. <u>Amphibians as Laboratory Animals</u>, ILAR Journal, Vol. 37, No. 4, 1995 http://dels.nas.edu/ilar_n/ilarjournal/37_4/37_4Amphibians.shtml
- Amphibians: Guidelines for the Breeding, Care, and Management of Laboratory Animals. National Academy of Sciences, Washington, DC, 1974 – Contact <u>IACUC Administrator</u>
- <u>Guidelines to the Use of Wild Birds in Research</u> (Ornithological Council) http://www.nmnh.si.edu/BIRDNET/GuideToUse/index.html
- <u>AVMA Guidelines on Euthanasia</u> http://www.avma.org/issues/animal_welfare/euthanasia.pdf
- Bowman, Phil J., A Flexible Occupational Health and Safety Program for Laboratory Animal Care and Use Programs, AALAS Bulletin, Vol. 30, No. 6, November 1991, pps. 15-17.
- Occupational Health and Safety in the Care and Use of Research Animals. National Research Council, Washington, DC, 1977 Contact <u>IACUC Administrator</u>

Training Resources:

- <u>PHS Policy on Humane Care and Treatment of Animals Tutorial</u> http://grants.nih.gov/grants/olaw/tutorial/index.htm
- <u>What Investigators Need to Know About the Use of Animals</u> http://grants.nih.gov/grants/olaw/InvestigatorsNeed2Know.pdf
- <u>CITI Lab Animal Welfare Course</u> http://www.citiprogram.org
 - Working with the IACUC for investigators, students and Staff
 - Essentials for IACUC Members
 - Post-Procedure Care of Mice and Rats in Research: Reducing Pain and Distress
 - Working with Amphibians in a Research Setting
 - Working with Mice in Research Settings
 - Working with Rats in Research Settings
 - Working with Hamsters in Research Settings
 - Working with Gerbils in Research Settings
 - Working with Guinea Pigs in Research Settings
 - Working with Rabbits in Research Settings