VALDOSTA STATE UNI VERSITY A4578-01

Animal Welfare Assurance for Domestic Institutions

I, James T. LaPlant, Ph.D., Interim Assistant Vice President for Research and Dean of the Graduate School, as named Institutional Official (IO) for animal care and use at Valdosta State University (VSU), provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS. This Assurance covers only those facilities and components listed below.

III. Institutional Program for Animal Care and Use

A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are as follows:

See Attachment 1

- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:
 - 1) Name: Teresa H. Doscher (Attending Veterinarian)

Qualifications

Degrees: B.S., D

Training or experience in laboratory animal medicine or in the use of the species at the Institution:

Training and experience varies. However, all participating veterinarians have a small animal practice and are experienced in treating pet rodents and in American te(si)4(t8si)4(

3) Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

During program review and facilities inspection, the IACUC Administrator, Research Compliance Specialist, and/or the IACUC Chair serve as recorders as IACUC members utilize the OLAW check lists to perform the program review and inspections. The Research Compliance Specialist prepares official final checklists and the summary Semiannual Program Review and Facility Inspection Report form for review by the IACUC members at the next convened meeting at which a quorum is present.

The Semiannual Program Review and Facility Inspection Report notes that the review and inspection ha Guide for the Care and

Use of Laboratory Animals, Eighth Edition, in accordance with the U.S. Public Health Service Policy on the Humane Care and Use of Laboratory Animals and the Animal Welfare Act, 9CFR 1, Section 2.31. It includes minor and significant deficiencies in the program or facilities; an action plan to remedy each deficiency; notation of the person responsible for ensuring action on the remediation plan; and a target date for remediation. Any corrections noted at the meeting are made by the Research Compliance Specialist and are initialed by the IACUC Chair. The report notes any IACUC approved departures from the Guide, PHS Policy, or the Animal Welfare Act and reasons for each departure; if there are no departures, the report states such. Similarly, any minority views are incorporated as an attachment; if there are no minority opinions, the report will state such. The Semiannual Program Review and Facility Inspection Report is signed by a majority of voting IACUC members and is forwarded to the IO by the Research Compliance Specialist. The original report and checklists are maintained in the Office of Sponsored Programs & Research Administration as part of the official IACUC files.

4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

The IACUC has a SOP for reviewing concerns about noncompliance with regulations, policies and procedures, and approved protocols. The SOP is maintained on the IACUC website and information about its existence is posted in each animal facility.

The SOP defines various types of noncompliance that may be reported. Noncompliance is generally defined as failure of the investigator/instructor involved in animal activity to follow applicable laws, regulations, policies, procedures, approved protocols, and/or directives of the IACUC or the Attending Veterinarian. Acts of noncompliance are classified as injurious, non-injurious, and administrative. The three classes of noncompliance are not mutually exclusive. In terms of actions that the IACUC may take to ensure the well-being of animals used in research, testing, and instruction, one type of noncompliance is not necessarily more serious than another and all may result in corrective and/or punitive actions.

Injurious noncompliance occurs when an investigator/instructor conducts a painful, distressful, or invasive procedure on an animal without IACUC approval or when the investigator/instructor does not follow procedures approved by the IACUC, resulting in increased risk of animal pain, distress, morbidity, or mortality. Examples of injurious noncompliance include, but are not limited to:

Performing unauthorized surgery;

Performing surgery or other painful procedures without proper anesthesia;

Performing unapproved repeated survival surgery;

Excessive use of restraints;

Use of drugs not previously approved for the protocol;

Use of unapproved methods of euthanasia:

Permitting untrained and/or unauthorized personnel to perform invasive or potentially painful or distressful procedures;

Failing to inform the Attending Veterinarian in a timely manner of unexpected adverse

a special meeting is called to review the AUP. Likewise, if any DMR reviewer refers an AUP for FCR, it is placed on the agenda for the next convened IACUC meeting, or, if conditions warrant, a special meeting is called to review the AUP.

d. Designated Member Review (DMR) Subsequent to Full Committee Review (FCR):

If all voting members are present at the meeting at which a FCR takes place and changes to the AUP are determined to be required, the IACUC may, by majority vote, approve subsequent review and approval by DMR, with the Chair appointing the designated reviewer(s) from the voting membership (excluding the Attending Veterinarian). Alternately, the IACUC may vote to return the AUP for FCR at the next convened meeting.

If any IACUC voting members are absent from the meeting in which the FCR takes place and modifications are requested, the IACUC may vote either to have the revised AUP returned for FCR during the next convened IACUC meeting or to employ DMR procedures. If DMR procedures are elected, the revised AUP is distributed electronically to all IACUC members, including those not present at the convened meeting at which the AUP was initially reviewed. Any IACUC voting member may call for the revised AUP to be referred for FCR at the next convened meeting of the IACUC. If no voting member requests FCR of the revised AUP, the IACUC Chair appoints the designated reviewer(s) from the voting membership (excluding the Attending Veterinarian). The DMR team may continue to request additional information from the animal user, through the Research Compliance Specialist, until they either unanimously approve the AUP or refer it for a second FCR.

e. Review Guidelines:

IACUC members who are affiliated with a protocol in a way that presents a potential or actual conflict of interest are recused from reviewing and voting on actions related to that protocol. If a conflict of interest is questionable, the IACUC Chair determines whether the member is should be recused. During FCR, a quorum must be maintained after any member is recused in order for the IACUC to take action.

Regardless of the type of review, IACUC members utilize the *Guide*, the AVMA Guidelines on Euthanasia, and generally accepted specialty guides for specific species used at the Institution in their deliberations.

DMR approvals of new protocols are reported at the next IACUC meeting.

A protocol may be disapproved only by vote of a majority of members of a convened meeting of the IACUC at which a quorum is present.

7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

Animal users are required to submit to the IACUC, through the Research Compliance Specialist, any significant proposed modifications of previously approved AUPs following review by the Attending Veterinarian. The Research Compliance

If no IACUC member calls for FCR, the IACUC Chair will appoint one or more designated reviewer(s) from among the voting membership (except the Attending Veterinarian). If the reviewer(s) need additional information from the animal user or if a change to the proposed AUP modification is required, the Research Compliance Specialist co

response is submitted to the Research Compliance Specialist, who forwards it to the designated reviewer(s). This back-and-forth communication continues until the animal user has addressed all questions and concerns, at which time the designated reviewer(s) may unanimously approve the modification or refer it for FCR. At any time during this process, however, any designated reviewer may individually refer the AUP for FCR for consideration and disposition.

b. Full Committee Review (FCR) of AUP Modifications:

If any IACUC voting member requests a full committee review of a proposed AUP modification, it is placed on the agenda for the next convened IACUC meeting, or, if conditions warrant, a special meeting is called to review the AUP. Likewise, if any designated reviewer refers an AUP for FCR, it is placed on the agenda for the next convened IACUC meeting, or, if conditions warrant, a special meeting is called to review the AUP.

c. Designated Member Review (DMR) of an AUP Modification Subsequent to Full Committee Review (FCR):

DMR approvals of protocol modifications are reported at the next IACUC meeting.

A protocol modification may be disapproved only by vote of a majority of members of a convened meeting of the IACUC at which a quorum is present.

8) Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Ins

employed for any other new AUP.	This ensures that a continui	ng animal activity undergoes a
complete review at least once ever	y three years.	

source of funds that supports

If the suspended animal activity involves PHS

remains in the facility except when being cleaned. Eating, drinking, and smoking are prohibited in all animal facilities and classrooms during animal activity. Failure of animal workers to comply with health and safety requirements is grounds for termination of employment

- Animal workers are required to report allergic reactions to the animals or their environment to their supervisor. Such reports may generate an occupational health duties.
- i. When an animal worker incurs a bite wound or other injury or is exposed to potentially
 - required to immediately report to Student Health Services for first aid (and for treatment if he/she is a student) and, as necessary, a nearby family medicine walk in clinic for care, or the local hospital for emergency or after-hours care. In the event of injury in the field, the individual is instructed to report to the nearest hospital emergency room for treatment. Immediately thereafter, if not done already, the injured individual is required to report the incident to his/her supervisor/faculty advisor, the IACUC Administrator, the Office of Environmental and Occupational Safety, and (if an employee) the Office of Human Resources for assistance with a Workers Compensation claim.
- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.

See Attachment 3

G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

All animal users (faculty, students, and employees) have access to the CITIProgram Animal Care and Use (ACU) courses (including the *Working with the IACUC* basic and refresher courses), and this resource is heavily used. The modules address such topics as working with the IACUC, federal mandates, veterinary consultation, alternatives to animal use, avoiding unnecessary duplication, endpoint criteria, surgery, blood sampling, personnel training, health and safety issues, use of hazardous and toxic agents in animals, animal housing, euthanasia, protocol modification, and reporting animal care and use concerns. Additionally, animal users have the opportunity to review species and procedure specific modules.

The Animal Use Proposal (AUP) application requires all applicants to explain in detail how the number of animals to be used was determined, what alternatives to animal use were considered, and what database searches were conducted to ensure non-duplication. Included in the AUP are questions which address the level of distress and pain the researcher anticipates the animals will experience and techniques to be used to minimize pain and distress. Specific questions about prolonged loss of sensation or paralysis, prolonged physical restraint, non-standard husbandry techniques, removal of the animals from the immediate care facility, and expected adverse effects or overt signs of illness are also posed. Researchers studying stress, pain, or abnormal behavior in live animals which cannot be alleviated with drugs because their use would interfere with the research goal must provide clear rationale. In its review, the IACUC focuses on minimizing animal numbers to obtain valid results and on minimizing pain and distress.

Investigators are responsible for training student assistants and other animal care staff in protocol-specific techniques, with consultation and assistance from the Attending Veterinarian and oversight of the IACUC as needed. The IACUC may also require the Principal Investigator to obtain specialized training before an AUP is approved. Details regarding past training/experience and additional training needs are documented in the AUP.

All IACUC voting members complete the CITIProgram module, *Essentials for IACUC Members*, and are strongly encouraged to complete investigator modules, including appropriate species specific modules. Additionally, IACUC members are provided with electronic access to the *Guide*, the OLAW/ARENA IACUC Guidebook, PHS Policy, the Animal Welfare

species (e.g., Guidelines of the American Society of Mammologists for the Use of Wild Animals in Research, Journal of Mammology, Vol. 92, No. 1, 2011; Guidelines for the Use of Fishes in Research, American Fisheries Society, the American Institute of Fisheries Research Biologists, and the American Society of Ichthyologists and Herpetologists, 2004; Guidelines for Use of Live Amphibians and Reptiles in Field and Laboratory Research, American Association of Ichthyologists and Herpetologists; and others)

New IACUC members are provided with an overview of IACUC activities and responsibilities by the IACUC Chair and/or the IACUC Administrator. This includes a general history and purpose of the IACUC; an overview of USPHS and USDA regulations; a review of the IACUC web page that includes the Assurance, Standard Operating Procedures, and links to *Guide*, PHS Policy, the Animal Welfare Act and USDA regulations, the OLAW/ARENA IACUC Guidebook, and other resources. When newer members serve as designated reviewers, they do so with more seasoned members who guide them through the review process.

IV. Institutional Program Evaluation and Accreditation

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the *Guide*. Any departures from the *Guide* will be identified specifically, and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. itutional Official. Semiannual

F. Institutional Endorsement and PHS Approval	

G. Other Key Contacts

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

Attachment 3

Facility and Species Inventory

Date: February 18, 2013

Name of Institution: Valdosta State University

Assurance Number: A4578-01

Laboratory, Unit, or Building

Gross Square Feet [include service areas] Species Housed [use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog]

Approximate Average Daily Inventory