# UNIVERSITY OF LOUISIANA AT MONROE A3641-01

### **Animal Welfare Assurance for Domestic Institutions**

I, Eric Pani, as named Institutional Official for animal care and use at University of Louisiana at Monroe (ULM), 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.

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:

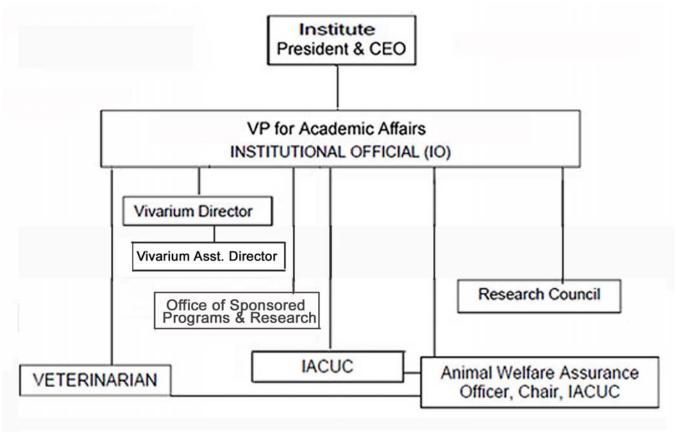
  ULM School of Pharmacy Animal Vivarium. 1800 Bienville Dr., Monroe, LA 71201.
- B. The following are other institution(s), or branches and components of another institution: None

#### II. Institutional Commitment

- A. This Institution will comply with all applicable provisions of the <u>Animal Welfare Act</u> and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "<u>U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training</u>."
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals* (*Guide*).
- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

# 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:



- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:
  - 1) Name: Dr. Brent White Qualifications
    - Degree: D.V.M., 1997, School of Veterinary Medicine, Louisiana State University
    - Training and/or experience in laboratory animal medicine: Dr. White has been in private practice in Monroe since graduation. He has special interest in small animal medicine, surgery, canine, feline, avian and exotic animals.

Authority: Dr. Brent White has delegated program authority and responsibility for the Institution's animal care and use program including access to all animals.

#### Time contributed to program:

Dr. White works with the University under contract to provide consultation and veterinary services to laboratory animals. Dr. White's time at the Institution, which is 100% committed to the animal care and use program, varies with the needs of the program, minimally ~1 hr/mo. On-site activities minimally include semi-annual inspections of all laboratory animal care facilities and preparation of reports of deficiencies and recommendations for improvement and/or needs for future facility improvement. Dr. White consults with each animal caretaker on methods and procedures and preparation of standard operating procedures (SOPs). As an IACUC member, Dr. White meets at a minimum with the IACUC semi-annually during which he participates in protocol reviews and animal facilities inspections.

Dr. White also expends unscheduled time to advise the IACUC on protocols by email correspondence. He is available on an on-call basis. If Dr. White is not available, Dr. Sara Groan, serves as his back-up.

2) Name: Dr. Sara Groan

Qualifications

- Degrees: D.V.M., 2001, School of Veterinary Medicine, Louisiana State University
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Dr. Groan is a private practitioner who works with Dr. White. She has experience in small animal medicine and surgery. Dr. Groan further interacts with the ULM School of Pharmacy in teaching ULM's PHRD 5063, Veterinary Pharmacotherapy (3 cr. hr), an elective for 2<sup>nd</sup> yr PharmD students.

#### Responsibilities:

Dr. Groan is contracted to provide ULM on-call veterinary needs for the animal program in Dr. White's absence.

Time contributed to program: Varies.

3) Person assigned daily management of animal use & care and facility management.

Name: Mr. Cody Lee, RALT. B.S.

Vivarium Assistant Director

C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

#### D. The IACUC will:

- 1) Review at least once every 6 months the Institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:
  - ULM IACUC meets April and October of each year and reviews the Institution's program as aided by the OLAW checklist (<a href="http://grants.nih.gov/grants/olaw/sampledoc/cheklist.pdf">http://grants.nih.gov/grants/olaw/sampledoc/cheklist.pdf</a>). Reports on the following areas (responsible party) are presented:
  - a. Veterinary Care (Dr. White; Vivarium Asst. Dir., Mr. Lee)
  - b. IACUC function, ULM animal program (IACUC chair, Dr. Meyer)
  - c. Occupational HIth (Mr. Lee)
  - d. Personnel training (Dr. Meyer)
  - e. Infrastructure issues (Mr. Lee)
- 2) Inspect at least once every 6 months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

The IACUC inspects the animal housing facilities in conjunction with semiannual meetings. Inspection items include appropriateness and adequacy of the physical environment - as aided by the OLAW checklist - as follows:

- a. Animal housing of mice and rats on trials housed in either shoebox cages or cages of isolator units. All holding rooms that contain cages are checked for appropriate cage size, number of animals per cage and the separation of species.
- b. Environment appropriate temperature, humidity and light/dark cycles are being maintained in the holding rooms. Also, the appropriate number of room air changes per hour is being maintained. In our facility, this is 12-15 complete room air changes per hour. The air used is 100% fresh air.
- c. Food and bedding ensure the quality of food and bedding. Harlan Teklad LM 485 sterilizable mouse/rat diet is used unless a protocol specifies a special diet. Harlan Teklad Laboratory Grade Sani-Chips are used unless the protocol specifies another type of bedding. A representative number of cages in each holding room is checked for: 1) adequate and available food, 2) clean bedding and evidence of regular changes, and water availability and working condition of the bottles and sipper tubes.

- d. Population management each holding room is checked to insure that all cages have cage cards with, at a minimum, the following information:
  - 1) Animal source, 2) Strain, 3) Investigator(s) name, 4) Number of animals and
  - 5) IACUC-assigned protocol number
- c. Waste Disposal records are checked as to the disposition of animal wastes. Storage facilities for carcasses are checked for adequacy and function. Facilities are also checked to verify that all radioactive wastes are stored separately and that disposal is by a licensed contractor.
- d. General facility condition the general condition and upkeep of the ULM vivarium is observed and noted. Storage facilities are checked for adequacy and appropriateness (food and bedding are stored on raised palates, not on the floor; torn or otherwise opened food containers are removed and food not used in the facility). Any physical condition needing attention is noted and brought to the attention of the Vivarium director, the ULM Animal Welfare Assurance Officer and the Institutional Official.
- 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:

Semiannual memos are composed by the IACUC chair to the Institutional Official, i.e., Vice President of Academic Affairs (VPAA). The VPAA is informed that IACUC review of the institutional animal program and facilities is based upon requirements of PHS Policy and the *Guide*. The memo is reviewed and signed by all IACUC members. These memos summarize changes in IACUC membership and minutes of the previous IACUC meetings, approved by simple majority, to include activity on protocol approvals, program review and facilities inspection. Minority views and facilities deficiencies with remediation plans, if any, are recorded. Minor and significant program deficiencies and departures from the *Guide* are noted.

Departures from PHS Policy and the *Guide* are identified by IACUC in a protocol application when a project director's description includes procedures that do not comply with "must" statements of the *Guide*. For all instances where protocol approval is denied because of departure from the *Guide*, IACUC will consider a revised protocol with explicit justification for the departure based upon scientific value for the study's departure from the *Guide*. The project director is invited to present this justification to IACUC members in full committee meeting. The IACUC will only approve protocols with departures from the *Guide* when a majority concurs that the study presents sufficient scientific merit and value to advance knowledge that will improve human, environmental and ecological health.

Deficiencies during conduct of an IACUC-approved on-going project that are identified during post-approval monitoring by the on-site Vivarium assistant director and animal welfare issues are reported to the veterinarian who will immediately provide treatment or euthanasia, if conditions meet pre-specified protocol criteria, for illness, injury and to alieve pain and distress. Project director, project personnel, or facility staff will attempt to promptly correct the deficiency and IACUC chair will be notified of nonadherance to an approved protocol. For significant deficiencies. a special meeting of IACUC is convened to review the activities and revoke protocol approval, if justified as judged by a majority vote of a quorum.

Facilities malfunctions also will likely be discovered by on-site staff. If the deficiency is not readily resolved, the IACUC chair, in consultation with the Vivarium director and/or College Dean/Dept Head, will document the deficiency by memorandum to the responsible party (project director, facility manager, IO) by memorandum and suggest methods for remediation and an implementation timeline. Progress in resolving the deficiency will be monitored by on-site staff and reviewed at the next scheduled IACUC meeting and another memorandum issued, if necessary.

IACUC will determine whether deficiencies are minor or significant based upon whether a threat is posed to the health or safety of animals. The IO will be informed of the event and advised on need for notification of OLAW by memorandum from the IACUC chair.

For all of these proceedings, member responses are anonymously documented in the minutes. Alternately, IACUC members may give written responses at the Animal Assurance Officer's request for issues that arise outside of scheduled meetings.

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

An SOP to guide in reporting animal welfare concerns is posted to the ULM Vivarium web site (<a href="http://www.ulm.edu/pharmacy/vivarium.html">http://www.ulm.edu/pharmacy/vivarium.html</a>). A form to accommodate description of the concern is appended to the SOP that is to be routed to the institutional investigating personnel and IACUC chair for entries to directed questions, dates and signatures.

The Chair of the IACUC, the Vivarium director and/or assistant director, the consulting veterinarian or any other member of the IACUC may receive any concerns in written form, electronic form, telephone call or personal communication. Any such communications/concern is handled in the most discrete manner possible to protect the anonymity of the individual reporting the concern and prevent any possibility of reprisal. Only the person receiving the concern, the University Animal Welfare Assurance Officer and the Institutional Official are on a "need-to-know" basis concerning the identity of the individual presenting the concern unless the situation, as determined by the Institutional Official, warrants others to be included in that information loop.

The concern will be presented to the Vivarium assistant director for investigation, discussion and disposition. If the concern is a valid issue, the ULM Vivarium director will be instructed to correct the problem. If moribund animals are involved, the assistant director will euthanize the animals in consultation with the veterinarian. In the event that the resolution of such concerns exceeds the ability of the ULM Vivarium Director and the Vivarium staff, the University Animal Welfare Assurance Officer will be notified of the situation and the Institutional Official will be consulted as to the most appropriate route of resolution. The Institutional Official will be informed of the event and progress in resolution by memorandum.

5) Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

Based upon reports [section D.1)] given at regular meetings or specially called meetings, the IACUC makes written reports through memorandum detailing aspects of ULM's animal program, facilities or personnel training to the Institutional Official. The ULM Office of Sponsored Programs and Research (OSPR) is copied on these memos to inform the institute of extramurally funded post-award compliance activities. The latter office manages ULM's on-line training of project directors and their staff in animal care and use through the Collaborative Institutional Training Initiative (CITI, University of Miami).

6) Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:

The IACUC chair receives and distributes to its members electronic copies of animal welfare assurance applications by email throughout the year as they are received for review. Protocol applications received by the IACUC chair must be signed by the PI's Department Head and Dean before distribution. After 1 week, the IACUC chair either a) refers the protocol to the full committee for review if coincident with the semiannual meeting, or b) circulates protocol by email to all IACUC members to determine whether any member has concerns that significant problems may justify denial of approval. If a member expresses concern, the chair will convene a meeting of the full IACUC to review that protocol.

Designated Member Review (DMR): If no IACUC member expresses concern, the IACUC chair assigns the protocols to a qualified IACUC member ("designated member review"). The DMR then recommends approval, modifications to secure approval or referral of the application for full committee review. Content of past protocols have been such that a single DMR has proved sufficient; however, if multiple DMRs are required in the future, the DMRs will review identical copies of the application and will exchange their opinions by email. If consensus is achieved, they will forward their opinion to approve, require modifications to secure approval or recommend full committee review to the Chair. If modifications to secure approval are recommended, the Chair will forward the information by memorandum to the project director who will then submit a modified application. Identical copies of the modified application will be forwarded to the DMRs who will exchange opinions of modification requests have been adequately addressed. If consensual, DMRs can approve the revised

protocol. If DMRs are unable to reach consensus, the IACUC chair will submit the proposal to full committee review at the next semi-annual meeting.

For <u>full committee review</u> (FCR), a simple majority vote at a convened IACUC meeting of a quorum of members may vote to approve a protocol or to withhold protocol approval. In addition, any member can recommend modification to secure approval to the full committee. If a majority of the quorum of members at a convened committee concurs through a formal vote with the requested modification, the protocol is returned to the investigator by the IACUC Chair with instructions on how to modify the protocol.

Revised protocol must be signed by the PI's Department Head and Dean before distribution to IACUC members by email by the Chair. After 1 week, the IACUC Chair either a) refers the protocol to the full committee for review and approval if coincident with the semiannual meeting or if called for by any member during the preceding week or b) if no member has concerns that warrant calling a convened meeting, arranges for review and approval by DMR, which will include the committee member that requested the modification to the original proposal.

Protocol reviews focus on: 1) rationale and purpose of the proposed use of animals, 2) justification of the species and number of animals, 3) availability and/or appropriateness of the use of alternative procedures which are less invasive or could substitute for the use of animals, 4) appropriateness of experience and training of the project director and other personnel involved in the protocol, 5) unusual housing and husbandry requirements, 6) appropriate use of sedation, analgesia and anesthesia, 7) unnecessary duplication of experiments, 8) use of multiple major operative procedures, 9) criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated, 10) postoperative and/or post-procedure care, 11) method of euthanasia and animal disposition and 12) safety of working environment for personnel.

IACUC members who are project directors for an animal welfare protocol application are excused from full committee meetings during deliberation of their protocols and leave the meeting room to avoid conflict of interest. Recusal of a proposal Project Director that is an IACUC member during review of that proposal will leave 4 of the 5 full members; hence, this procedure for avoidance of conflict of interest does not pose a problem with insufficient members to provide a quorum. Decisions on protocol are made by voice vote and approval requires a majority. Expedited reviews are managed through email distribution of applications and, if no comments are forwarded within a week, by review by a member designated by the IACUC chair (DMR).

After DMR or FCR, if there are no concerns the Chair's signature on the protocol application form will indicate IACUC approve the protocol.

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:

The IACUC chair receives and distributes to the members of the IACUC for review an amended protocol form explicitly describing any significant changes in a previously approved animal protocol. Amended protocol applications received by the IACUC chair must be signed by the PI's Department Head and Dean before distribution. If no concerns are expressed within a 1-week review period, the designated IACUC reviewer of the original can approve the amended protocol. If the IACUC members review the protocol and any member feels that there are problems significant enough to deny approval, that member can request review of the modified protocol at a full IACUC meeting. Only a simple majority vote at an IACUC meeting of a quorum of members may deny approval of significant changes to an active protocol.

Any member can inform the full committee of modification to secure approval. If a request for modification is made for a proposal submitted between scheduled full committee meetings, the IACUC chair will distribute the concern and suggested modification to all committee members and allow a 1-week comment period. If a majority of the committee concurs with the requested modification, the protocol is returned to the investigator by the IACUC chair with appropriate instructions. Once modifications have been made, the protocol is re-reviewed by full committee or, if all members were in attendance at the original meeting, by designated member.

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 Institution of its decisions regarding protocol review are as follows:

When protocols are received, distributed for review and a decision is reached to approve, the IACUC designate or Chair signs and dates the animal welfare assurance protocol form, a protocol number is assigned and electronic copy prepared for archiving in the IACUC and the ULM animal use program database. The application form for the approved protocol with all original signatures is returned to the investigator as notification of approval.

When modification is requested, the IACUC chair notifies the investigator of suggestions for modification. Revised protocols are distributed to the IACUC or designated IACUC member for review. If the protocol is now acceptable with no concerns, the designated member or chair can approve the protocol as indicated by signature. The protocol is assigned a protocol number, electronic copy prepared and the signed form returned to the investigator as notification of approval.

For protocol applications for which a majority vote at a meeting of a quorum of IACUC members supports denial of approval, the IACUC chair notifies the principal investigator and provides written summarization of how, in the committee's reasoning, the proposal is noncompliant with PHS policy, directives of the *Guide* or this Assurance.

For significant deficiencies identified during post-approval monitoring, a special meeting of IACUC is convened to review the activities and withdraw protocol approval, if justified as judged by a majority vote of a quorum.

The ULM animal use program database is stored on a server maintained by the School of Pharmacy. The IACUC chair and assistant vivarium director have access to this drive, which is consulted for post-approval monitoring. A log of all approved protocols is updated semi-annually and a back-up copy is prepared. Approved protocol numbers are displayed by the investigator on animal cage cards.

The Institute is informed by IACUC in its semi-annual memorandum of the number of active, IACUC-approved protocols in effect.

- 9) Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:
  - a. Post-approval monitoring of animals on trial and of the facility is conducted daily by the Vivarium on-site assistant director. If deficiencies are noted and depending upon its nature and severity, the project director, veterinarian and IACUC chair are consulted. The IACUC conducts its oversight through review of reports and facilities inspections at semi-annual meetings. Special IACUC meetings are convened to oversee substantive issues that arise between meetings.
  - b. The ULM animal program includes only rats and mice bred for research, i.e., non-covered species. Hence, IACUC conducts complete review of the existing animal protocols on a three-year cycle. All animal protocols are to be reviewed by full committee review during the Fall meeting using criteria listed in the III.D. 6), 4<sup>th</sup> paragraph. Each IACUC member will receive copies of the protocols prior to the meeting for their review and comments. All protocols will then be discussed in the meeting and decisions made to continue, ask for modification or discontinue the protocol. The IACUC chair will report to outcomes of these reviews to the project directors. The Institutional Official is notified of any modified protocol or other action taken by the IACUC as described in a memo from the chair.
- 10) Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

A meeting of the IACUC is convened to review on-going activities where activities are identified by post-approval monitoring that depart from PHS policy or mandates of the *Guide* not approved by IACUC as scientifically justified departures. Suspension of the IACUC-approved animal protocol under which these activities are specified will result if approved by a majority vote of a quorum of the IACUC. The assistant director of the Vivarium is an ex-

officio member of IACUC and thus will be apprised of the need to implement the IACUC decision to disallow activities of the suspended protocol. If the outcome of this meeting results in protocol suspension, proceedings will be reported to the Institutional Official by memorandum from the IACUC chair. The IO will review the events with the IACUC chair and will submit a preliminary report of the incident to OLAW by email with follow-up reports as the situation is resolved. A summary report will be included in the annual report to OLAW. The IACUC chair will inform the individual investigator of the outcome of the review.

- E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:
  - 1) <u>Control and prevention</u> is largely implemented through training and surveillance. ULM has an occupational health and safety program (OHSP) established to cover all personnel which includes chemical hygiene, prevention of needle sticks, blood borne pathogens and ergonomic issues. Employees are required to complete a subset of training modules each quarter. Completion of a special module for animal care workers on "Zoonotic Diseases of Laboratory Rodents" is required biennially. Additional training of students by Vivarium staff related to facilities management is conducted before experimentation is allowed.

Animal handlers are required to wear personal protective equipment (PPE) to include gloves and lab coats while in the Vivarium. Biosafety BSL-2 level is achievable in each ward of the Vivarium through provision of a Class II biosafety hoods and contractual arrangements for biohazard disposal. Surveillance is achieved during daily walk-throughs by facility staff and semi-annually by IACUC. Service and maintenance contracts are maintained on specific equipment, such as small animal anesthesia vaporizers, biosafety hood certification, HVAC, autoclaves, etc. The ULM Vivarium is a secure facility accessible with electronic keycard. A disaster plan SOP is posted to the Vivarium web site (http://www.ulm.edu/pharmacy/vivarium.html).

- 2) <u>Hazard identification and risk assessment</u> for the facility in general is part of training provided by Vivarium staff. For specific research projects, it is the responsibility of the project director to instruct his/her research technicians, undergraduate and graduate students and post-doctoral associates concerning the use of hazardous substances in the experimental design and protocol for animal use. Protocol applications identify personnel specifically trained to work with project hazards. Risk of project-specific activities such as chemical, biological hazards and radioactive hazards will be communicated to personnel by the project director. IACUC protocol approval requires copies of approval documents from other institutional units that oversee specific hazards to accompany protocol applications. These include ULM's Radiation Safety and Institutional Biosafety Committees. Hazardous chemicals to be used in a protocol are identified on the application form and, if warranted, the School of Pharmacy (SoP) Chemical Hygiene/Safety Officer is consulted.
- 3) <u>Facilities, procedures, and monitoring</u>. Monitoring of compliance with protocols to contain risk from chemical, biological and radiological activities associated with animal experimentation in the ULM Vivarium is the responsibility of the Vivarium assistant director. Issues related to facilities and procedures that affect occupational health and safety are detected by the Vivarium assistant director and reported to the SoP safety officer. If nonadherence of IACUC-approved protocols occurs, chairs of the relevant approving units will be notified and procedures followed for review and withdrawal of protocol approval implemented, if warranted.
- 4) <u>Personnel training</u> Instruction in chemical safety and working with physical and biological hazards, the latter including zoonoses and allergens, are provided via routine ULM quarterly safety meetings. Participation is documented by signature and completion of a short quiz. Procedures for handling of waste materials are presented during safety meetings to include those consistent with protocols of chemical and biological waste disposal contractors hired by ULM. Specific procedures required to protect high risk groups, such as pregnant women and immunocompromised workers are presented within the content of topic-specific safety meetings. Identification of high risk individuals is through self-reporting to the project director and ULM SoP safety officer, who maintain this information confidential.

- 5) <u>Personal hygiene</u> all workers are instructed concerning appropriate hand washing and use of PPE. Personnel are not permitted to eat, drink, or apply cosmetics in animal rooms. A separate locker room facility is provided for such activities in the animal facility. Showers and toilets are available in the Vivarium.
- 6) <u>Animal experimentation involving hazards</u>. Use of chemical, biological and/or radiological hazards in animal protocol applications are reviewed by the SoP Chemical Hygiene Officer at IACUC's request and by ULM's Institutional Biosafety and Radiation Safety Committees. Evidence of approval by these units is required for IACUC protocol approval. If necessary for IACUC's requirements, protocol modification via procedures of section D.6, above will be employed in consultation with the other oversight units.

Anesthetic waste gas will be scavenged with charcoal canisters that are connected to the outflow of our small animal anesthesia vaporizer.

- 7) <u>Personal protection</u>. Training in the use of gloves, lab coats and general protective clothing required for handling rodents in the Vivarium will be provided by the assistant director. PPE requirements of specific projects and instructions for their use will be communicated by the project director. It is the responsibility of the project director to provide personal protective clothing except gloves, such head covers, overalls, and self-contained breathing apparatus if such provisions are needed for that particular protocol. Gloves and shoe covers are provided by the ULM CoP Vivarium.
- 8) Medical Evaluation and Preventive Medicine for Personnel The University recommends that participants on PHS projects related to the care and use of animals have an annual medical exam including a test for tuberculosis. Occupational hazards, including animal bites, scratches and allergies, will be recognized and methods and use of PPE for preventing and treating them are in place. Bite and scratch incidences are reported to and recorded by the Vivarium assistant director and/or the Animal Welfare Assurance Officer. The report is recorded on the Accident Report form for the Vivarium and the individual is escorted to the ULM Student Health infirmary or, if referred by ULM Student Health, to an occupational health clinic of a regional medical facility. Records of the incident disposition will be kept in the Vivarium and ULM Human Resources. Allergic reactions are reported to and recorded by the Vivarium assistant director. Medical records are kept by the institute of the attending physician or medical staff and copies are filed with ULM Human Resources. Records will be maintained confidentially if mandated by federal or state law. If the PHS project participant instead seeks medical care from a private practice physician of their choice, it is the responsibility of that individual to arrange such care.

Pre-employment medical evaluations consist of those required for students entering ULM and include vaccinations. Any new employee must either show proof of tetanus vaccination within the previous 5 years or receive a tetanus vaccination before starting to work in the Vivarium. If new full-time employees are hired, they will undergo a pre-employment physical including TB skin test. Personnel are instructed to notify their supervisors of potential or known exposures or of suspected health hazards and illnesses. As explained above, there are clear procedures for reporting all accidents, bites, scratches and allergic reactions.

Only rodents are housed in the ULM vivarium; Herpes B infection precautions do not apply.

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

Project directors, research and animal technicians, undergraduate and graduate students and post-doctoral associates are required to complete training materials describing humane care and treatment of research animals that ULM contracts from Collaborative Institutional Training Initiative (CITI, University of Miami). Required modules are "Reducing Pain and Distress in Laboratory Mice and Rats", "Working with Mice in Research", and/or "Working with Rats in Research Settings". Once successfully completed, users forward electronic copies of completion reports to the IACUC chair. These are stored in the IACUC program database on the SoP server;

access is restricted to the assistant Vivarium director and IACUC chair. Instructions for project-specific issues affecting humane animal use are provided by the project directors.

Instruction for conducting a power analysis and links to web-based free-ware for statistically determining optimal number of animals for valid testing for specific research objectives is detailed on the animal welfare assurance form used by project directors to apply for IACUC approval. This form is available on the ULM OSPR and Vivarium web pages (<a href="http://www.ulm.edu/research/iacuc.html">http://www.ulm.edu/research/iacuc.html</a>). Project directors are required to describe results of this analysis to justify animal usage on their protocol applications. Training on limiting pain and distress are included on CITI training.

IACUC members are required to complete the 3 CITI modules listed above plus a module "Essentials for IACUC Members". Electronic copies of completion reports are maintained by the IACUC chair. In addition, upon joining IACUC, the chair provides a CD with copies of ULM's approved Animal Welfare Assurance; the *Guide*, 8<sup>th</sup> ed.; PHS Policy guide; OLAW's Semiannual Program Review Checklist; and OLAW's IACUC Guidebook. Members are apprised of updates to these documents and other significant policy documents with links to web-based guidance as part of the "IACUC function" report [section D.1)b] at the semi-annual meetings.

CITI training is renewed every 3 years. ULM OSPR and CITI will inform users of their upcoming need to renew their training.

# 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. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category 2 — not accredited by the <u>Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)</u> & As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The report of the most recent evaluation (program review and facility inspection) is attached.

# V. Recordkeeping Requirements

- A. This Institution will maintain for at least 3 years:
  - 1. A copy of this Assurance and any modifications made to it, as approved by the PHS
  - 2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations
  - 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld
  - 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Dr. Eric Pani.
  - 5. Records of accrediting body determinations
- B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional 3 years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

## VI. Reporting Requirements

- A. The Institutional reporting period is the calendar year (January 1 December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:
  - 1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
  - 2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
  - 3. Any change in the IACUC membership
  - 4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Dr. Eric Pani.
  - 5. Any minority views filed by members of the IACUC

If there are no changes to report, this Institution will provide written notification that there are no changes.

- B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
  - 1. Any serious or continuing noncompliance with the PHS Policy
  - 2. Any serious deviations from the provisions of the Guide
  - 3. Any suspension of an activity by the IACUC
- C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.

# VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official			
Name: Dr. Eric Pani			
Title: Vice President, Academic Affairs			
Name of Institution: University of Louisiana at Mo	nroe		
Address: (street, city, state, country, postal code) 700 University Ave., Monroe, LA, USA, 71209-0600			
Phone: 318-342-1025	Fax: (318) 342-1034		
E-mail: pani@ulm.edu			
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.			
Signature:	Date:		
B. PHS Approving Official (to be completed by OLAW)			
Name/Title: Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6705 Rockledge Drive RKL1, Suite 360, MSC 7982 Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163 Fax: +1 (301) 915-9465			
Signature:	Date:		
Assurance Number:			
Effective Date:	Expiration Date:		

#### VIII. Membership of the IACUC

Date: May 12, 2015

Name of Institution:

University of Louisiana at Monroe

Assurance Number: A3641-01

### **IACUC Chairperson**

Name\*: Sharon A. Meyer

Title\*: Associate Professor Degree/Credentials\*: Ph.D.

Address\*: (street, city, state, zip code)

Department of Toxicology, College of Health and Pharmaceutical Sciences

University of Louisiana at Monroe, 1800 Bienville Ave

Monroe, LA 71201

E-mail\*: meyer@ulm.edu

Phone\*: 318-342-1685 Fax\*: 318-342-1606

#### **IACUC Roster**

Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Benny Blaylock	Ph.D.	Vivarium Director	Ex officio (non-voting)
John Carr	Ph.D.	Professor	Scientist
Keith Jackson	Ph.D.	Associate Professor	Scientist
Seetharama Satyanarayana-jois	Ph.D.	Associate Professor	Scientist
Steve Tolson	M.S.	Retired, Biology Instructor	Nonscientist, Nonaffiliated
Brent White	D.V.M.	Veterinarian	Veterinarian
Leonard J. Clark	Ed.D.	Dir, OSPR	Ex officio (non-voting)
Coty Lee	LAT	Assistant Vivarium Director	Ex officio (non-voting)

<sup>\*</sup> This information is mandatory.

<sup>\*\*</sup> Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

\*\*\* List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

\*\*\*\* PHS Policy Membership Requirements:

Veterinarian with training or experience in laboratory animal science and

medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals

at the institution.

Scientist practicing scientist experienced in research involving animals.

Nonscientist member whose primary concerns are in a nonscientific area (e.g., ethicist,

lawyer, member of the clergy).

Nonaffiliated individual who is not affiliated with the institution in any way other than as a

member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not

be considered nonaffiliated.

# IX. Other Key Contacts (optional)

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

Contact #1			
Name:			
Lawanna Gilbert-Bell			
Title: Post Awards Grant Manager, Sponsored Programs and Research			
Phone: (318) 342-1039	E-mail: <u>lbell@ulm.edu</u>		
Contact #2			
Name:			
Title:			
Phone:	E-mail:		

# X. Facility and Species Inventory

Date:			
Name of Institution:	University of Louisia	ana at Monroe	
Assurance Number:	A3641-01		
Laboratory, Unit, or Building <sup>*</sup>	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
Vivarium	10501	Mice	150
		Rats	250

<sup>\*</sup>Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.



# DEPARTMENT OF HEALTH and HUMAN SERVICES

#### PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive
RKL 1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive, Suite 360
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

Date: September 10, 2015

Reference: Animal Welfare Assurance Approval Letter for #A3641-01

Dr. Eric Pani Vice President, Academic Affairs Institutional Official University of Louisiana at Monroe 700 University Avenue Monroe, LA – USA 71209-0600

Dear Dr. Pani:

I am pleased to inform you that The Office of Laboratory Animal Welfare (OLAW) reviewed and approved the renewal of your institution's Animal Welfare Assurance (Assurance) that was submitted in compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), as revised August 2002.

Your Assurance renewal, number A3641-01, became effective on September 10, 2015 and expires on September 30, 2019. This Assurance supersedes all previously issued Assurances. *Please include the Assurance number in all correspondence to OLAW*. A copy of the Assurance signature page is enclosed.

The Assurance is a key document in defining the relationship of your Institution to the PHS. It sets forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals. Among the important elements of the Assurance, I would especially call your attention to the reporting requirements that are essential for continued compliance with the PHS Policy. Please note that a Report to OLAW is required at least once every 12 months. The reporting period is the calendar year. Reports, for the previous calendar year, are due **January 31**.

Sincerely,

Venita B. Thornton, DVM, MPH

Senior Assurance Officer

Office of Laboratory Animal Welfare

CC:

IACUC Chairperson
Regulatory Compliance Officer / Administrator

# VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official		
Name: Dr. Eric Pani		
Title: Vice President for Academic Affairs		
Name of Institution: University of Louislana at Mo	nroe	
Address: (street, city, state, country, postal code) 700 University Ave., Monroe, LA, USA, 71209-0700		
Phone: 318-342-1025	Fax: (318) 342-1034	
E-mall: pani@ulm.edu		
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.		
Signature: Lub	Date: 8/18/15	
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B. PHS Approving Official (to be completed by	OLAW)	
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Venita B. Thornton, D.V.M., M.P.H. Senior Assurance Officer, Division of Assurances Office of Laboratory Animal Welfare (OLAW) NIH/OD/OER 6705 Rockledge Drive RKL 1, Suite 360-MSC 7982 Bethesda, Maryland 20892-7982 thorntov@od.nih.gov		
Signature: Cuta B hounton	Date: Sept. 10, 2015	
Assurance Number: $A364/-0/$		
Effective Date: Sent 10 2015 Expiration Date: Lent 30, 2019		