

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

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8/2/2016 Reference: Assurance Approval for **D16-00376** (# A3621-01)

Dr. James Dias Ph.D. Vice President for Research State University of New York- University of Albany University Hall 307B-1400 Washington Avenue Albany NY, 12222

Dear Dr. James Dias,

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

Your Assurance, identification number **D16-00376** (# A3621-01), became effective on **7/26/2016** and will expire on **7/31/2020**. Please include the Assurance number on all correspondence to OLAW. A copy of the signed Assurance document is enclosed. The signature page provides verification of approval by OLAW and specifies the period during which your institution's Assurance is effective.

The Assurance is a key document in defining the relationship of your Institution with 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 an Annual Report to OLAW is required at least once every 12 months. Annual Reports for the previous calendar year are due by January 31st. Your institution's Annual Report for reporting period 01/01/2016 through 12/31/2016 is due 01/31/2017.

If I may be of any further assistance, please do not hesitate to contact me.

Sincerely.

8/2/2016

X Venita B Thornton DVM, MPH

Signed by: PIV
Senior Assurance Officer

Office of Laboratory Animal Welfare

As stated

Enclosure:

Cc:

IACUC Chair



STATE UNIVERSITY OF NEW YORK UNIVERSITY AT ALBANY

INSTITUTIONAL ASSURANCE OF COMPLIANCE WITH PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS #A-3621-01

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Animal Welfare Assurance for Domestic Institutions

I, James A. Dias, as named Institutional Official for animal care and use at the University at Albany, hereinafter referred to as institution, by means of this document, provide assurance that this Institution will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals hereinafter referred to as PHS 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 PHS, DHHS, and/or NSF. This Assurance covers only those facilities and components listed below.

In this assurance, "Institution" refers to the University at Albany, State University of New York, and includes the major components of the University. These components are physically located on the University at Albany Main Campus and its East Campus.

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</u> Used in Testing, Research, and Training."
- 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. Lines of Authority

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

The president (CEO) of the University at Albany has delegated authority to the vice president for research (VPR) to serve as the Institutional Official (IO). The IO reports directly to the president. The IO is the official responsible for signing the Assurance and any Assurance amendments and annual reports to the Office of Laboratory Animal Welfare and the U.S. Department of Agriculture.

The University has an attending veterinarian who reports directly to the IO. The attending veterinarian is also the director of the Institution's Laboratory Animal Resources (LAR).

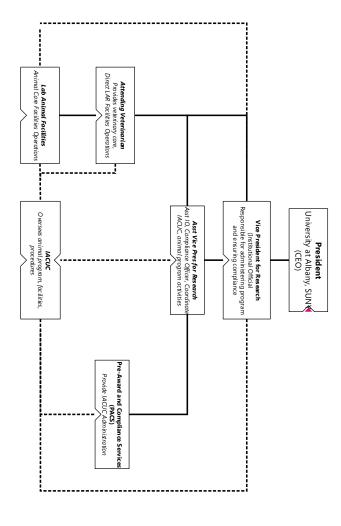
This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The Chair of the IACUC reports directly to the IO on all matters pertaining to the animal care and use program and works with Pre-Award and Compliance Services (PACS) for ensuring the proper execution of

the responsibilities of the Committee. The assistant vice president for research (AVPR) is also director of PACS and reports directly to the IO. The AVPR is responsible for coordinating the activities of the IACUC and overseeing PACS and LAR administration.

An organizational chart is provided below:

University at Albany Institutional Program for Animal Care and Use

The lines of authority and responsibility for administering the program and ensuring compliance with this policy are:



B. Qualifications and Authority of Veterinarian

program are as follows: The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the

The Institution's attending veterinarian is Antigone M. McKenna, DVM. Dr. McKenna is a graduate of the New York State College of Veterinary Medicine, Cornell University, Ithaca, NY. Dr. McKenna is a full-time employee of the University at Albany and devotes 100% of her time to the laboratory animal care program.

with the University Office of Environmental Health and Safety, the IACUC, the LAR facilities manager, and the immobilization, anesthesia, analgesia, surgery, post-surgical care, and euthanasia of animals; and consults health and welfare; consults with the animal care technicians regarding methods to prevent, control, diagnose, and treat diseases and injuries; consults with researchers regarding proper handling, Dr. McKenna has direct program authority and responsibility for the University at Albany animal care and use AVPR in the development and administration of training and educational programs The University's attending veterinarian (AV) inspects the animal facilities to assess the animals'

veterinarian to administer veterinary care. Arrangements have been established by Dr. McKenna with two unavailability, specific arrangements are made to ensure availability of a qualified, knowledgeable Dr. McKenna is on-call for emergencies, after hours, and weekends/holidays. In the event of Dr. McKenna's local clinical veterinarians: Douglas Cohn, DVM, and Karen Krause, DVM. Dr. Cohn and Dr. Krause serve on an on-call basis, as necessary.

- Dr. Cohn holds a Doctor of Veterinary Medicine degree from Cornell University and is an ACLAM diplomate. He has over 24 years of experience in all aspects of laboratory animal medicine. Dr. Cohn is contracted to provide back-up veterinarian coverage when Dr. McKenna is unavailable.
- Dr. Krause holds a Doctor of Veterinary Medicine degree from the University of Illinois. She has
 more than 16 years of experience in all aspects of laboratory animal medicine. Dr. Krause is
 contracted as a back-up veterinarian when Dr. McKenna and Dr. Cohn are unavailable.

For planned unavailability, Dr. McKenna will contact Dr. Cohn and/or Dr. Krause at least two weeks in advance to request back-up veterinary services. Upon confirmation of the request, Investigators are notified via email and notices are posted in each animal facility specifying the coverage dates and contact information for the back-up veterinarians.

In the event that Dr. McKenna is unexpectedly unavailable (i.e., unplanned), Dr. Cohn and/or Dr. Krause are contacted immediately by Dr. McKenna or the LAR facilities manager to request back-up veterinary services. Upon confirmation of the request, Investigators are notified via email and notices are posted in each animal facility specifying the coverage dates and contact information for the back-up veterinarian(s).

C. Appointment of IACUC

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. (See Part VIII for list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.)

D. Duties of the IACUC

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:

PACS schedules and coordinates the IACUC program review meetings semiannually, and is responsible for drafting the written reports. The IACUC program review is conducted at a meeting of a minimum of three IACUC members. All IACUC members are invited to the meetings and to participate. Those present also include PACS staff. Typically, the IO, AVPR, and the LAR facilities manager also attend. Each participating member is provided with OLAW's Sample Review Checklist as a guide and basis for the evaluation to ensure all program areas requiring review are covered. The program review includes:

- IACUC membership and functions:
- IACUC protocol review practices;
- IACUC records and reporting requirements;
- Veterinary care;
- · Research personnel qualifications and training; and
- Occupational health and safety of personnel.

The evaluation will include a review of the Institution's PHS Assurance. If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel. The IACUC will also review status

of items identified in past Reports so that the IACUC may review to determine how they have been addressed, and whether IO or IACUC follow-up is needed.

PACS will draft the report of the evaluation. If one or more categories or items under a category is/are rated as a minor or significant deficiency, the IACUC chair, with PACS, will pursue the concern(s), see that the concern(s) are addressed and report to the IO and IACUC the steps that were taken to correct the deficiency(ies) at the IACUC's next meeting. In the event of a substantive programmatic change recommendation, a subcommittee of the IACUC may be appointed by the Chair to further evaluate the recommendation and report back to the full IACUC for a determination. The Institutional Official is notified in this case.

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:

All University animal facilities are inspected. Areas inspected include, but are not limited to: cage wash; aseptic surgery; procedure areas; labs, necropsy; supplies and inventory storage; controlled substance storage and records; surgical suites; and recovery areas.

PACS creates a semiannual inspection itinerary, schedules inspection visits to laboratories and housing areas, escorts the inspection teams, and drafts the written report. The inspection team will consist of a minimum of two voting members of the IACUC. No IACUC member wishing to participate in any review or inspection shall be excluded. The subcommittee may invite ad *hoc* consultants to assist in the reviews and inspections. The inspection team will tour the animal facilities and PACS will summarize the team's findings, and draft the reports. The report will distinguish between significant and minor deficiencies and will be provided to the AV/LAR director, IACUC members, IO and AVPR as prepared. The AV/LAR director will respond to listed deficiencies in writing to the IACUC with a reasonable and specific plan and schedule for each deficiency for correction. The responses will subsequently be reviewed by the IACUC.

3- Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official.

Every six months, the AVPR prepares a written report on behalf of the IACUC. The report describes the University's adherence to the *Guide* and the Animal Welfare Act. All IACUC semiannual reports will include a description of the nature and extent of this institution's adherence to the *Guide*.

All departures from the *Guide* (including those approved by the IACUC) will be identified specifically and reasons for each departure will be stated. Departures will be reported for each six month reporting period during which an IACUC approved departure is in place.

All deficiencies will be stated, and the report 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. Any failure to adhere to the plan and correction schedule that results in a significant deficiency remaining uncorrected shall be reported by the IACUC through the IO to OLAW within 30 days and, as appropriate, to the Animal and Plant Health Inspection Service (APHIS). If the activity is federally funded, the relevant agency shall also be informed by the IO or (in his/her absence) the AVPR.

The draft semiannual report is distributed to all members of the IACUC for review and discussion at a convened meeting where a quorum is present. The report must be signed by a majority of the members of the IACUC. All minority views, if any, are included in the report.

The signed final semiannual report is submitted to the IO and copies are maintained by PACS and the LAR. The report shall be made available to USDA, OLAW, and any federal funding agencies upon request.

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

Concerns about any aspect of animal care and use at the University at Albany may be made to any member of the IACUC, LAR, PACS, IO, or via anonymous hotline. Anyone that desires to express a complaint regarding the treatment of animals under the university's care is encouraged to contact the IO, AV, IACUC chair, or the AVPR. Detailed contact information and instructions for submitting concerns (including via anonymous email form) are provided at http://www.albany.edu/orrc/report-concern.php. Information is also prominently posted in the LAR facilities. The IACUC and PACS will investigate any animal care and use concern, even if submitted anonymously. No adverse action will be taken against anyone making a good-faith report. No employee, committee member, student, or other person shall be discriminated against or be subject to any reprisal for reporting, in good faith, concerns or violations of regulations or standards under the Animal Welfare Act.

All complaints or concerns are communicated immediately to the IO by the IACUC chair, AV, or AVPR. Following receipt of a complaint or concern, the IACUC chair, AV, or AVPR will meet with the individual(s) against whom a complaint or concern is lodged. The purpose of this discussion is to allow the individual an opportunity to respond to the claim and to clarify any misunderstanding. If the claim is found to have merit, an inquiry will be conducted by a subcommittee of IACUC members. PACS participates in the fact-finding, to facilitate documentation and to ensure that the rights and reputation of the accused individuals are protected. In every case, PACS maintains a record of the concern, the investigator, resulting recommendation and resolution, and the report to the IO and to appropriate federal agencies.

Actions undertaken in response to a complaint or concern will be completed in a timely manner, based on the circumstances or seriousness of the noncompliance. Under federal regulations, the IACUC has the authority to temporarily or permanently suspend approval of an activity that is not being conducted in accordance with IACUC policies or federal requirements, or that has been associated with unexpected serious harm to animal health and safety. The IACUC chair, AV, or IO may temporarily stop any activity involving the use of animals and impose sanctions and/or secure critical documents at any time during or following an inquiry or investigation, if necessary, to ensure animal health and safety. The IO will assure that the necessary resources are available to conduct a thorough and timely review of all allegations of noncompliance. Suspension of a protocol may only be approved by the IACUC at a convened meeting.

Any suspension of an activity involving animals shall be immediately reported by the IO (or, in his/her absence, by the AVPR) to the Office of Laboratory Animal Welfare and, as appropriate, to APHIS and the federal agency funding the activity.

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

The IO attends semiannual program review meetings of the IACUC and is well informed regarding committee activities. Recommendations are presented and deliberated during committee meetings, and the IO is apprised of such discussions. When a formal action is addressed, a motion is made and seconded, and then the majority vote rules. Such action is communicated to the IO by letter, prepared by the AVPR on behalf of the IACUC and signed by the IACUC chair. The IACUC also utilizes the Semiannual Report to the IO for formally communicating recommendations; this document is signed by a majority of committee members.

6- Review and approve, require modifications (to secure approval), or withhold approval of those activities related to the care and use of animals according to PHS Policy IV.C.1-3. The following describes the steps to apply for IACUC approval.

✓ Protocol Preparation

Personnel (PI) proposing to use a live animals in research, training, education, experimentation, biological testing or for related purposes will consult with the AV with respect to planned activities for use of animals. PI will prepare an IACUC application form (hereafter referred to as protocol or submission). The forms and instructions are found on the PACS webpage at http://www.albany.edu/orrc/jacuc-forms.php

- Veterinary pre-review allows for the attending veterinarian or designee to review the protocol to ensure that any and all veterinary matters are addressed, analgesic and anesthetic dosages are correct, animal housing is appropriate, physical restraint is managed appropriately, and enrichment and exercise plans are being followed. Specific areas for veterinarian to focus on during pre-review that are discussed in the Animal Welfare Act Regulations and the Guide for the Care and Use of Laboratory Animals can include:
 - o Selection of appropriate analgesics and anesthetics
 - Development and implementation of humane endpoints
 - Provision of veterinary care when complications from physical restraint arise
 - Provision of environmental enrichment, in addition to the periodic review of enrichment program
 - Need to singly house animals
- The AV will verify that all key personnel listed in the protocol have up-to-date enrollment in the Occupational Health and Safety Program (OHSP). Final IACUC approval will be withheld until these requirements are satisfied.
- The AV will sign submission cover sheet.

✓ Protocol Submission

 The PI submits the IACUC submission, with all back-up documentation and attachments, to the IACUC via PACS.

✓ PACS Pre-Review and Processing of Submission

Submissions are logged into the IACUC Submissions database and assigned to a PACS Administrator to conduct pre-review.

The pre-review process focuses on administrative items such as whether or not all applicable protocol questions have been answered, ensuring that requests throughout the protocol are consistent, confirming that personnel have completed requisite training, and other relevant information as required. Submissions are also pre-reviewed for grant congruency, if grant funded, and to ensure compliance with applicable regulatory and institutional requirements. During this process, the PI may be asked to make revisions or provide additional information/documentation.

Funding Congruency

a. U.S. Department of Health and Human Services (HHS), primarily through the Public Health Service (PHS) and the National Institutes of Health (NIH). PHS and NIH Grants Policy requires the institution to verify, before award, that the

institution's IACUC has reviewed and approved the animal work outlined in the funding proposal. Specifically, "It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC." At UAlbany, PACS conducts a side by side direct comparison of the proposal and the IACUC protocol. For program consistency and to maintain the highest standards for compliance, the University at Albany applies these rules to all funding proposals regardless of source.

- b. All awards involving animal use requires IACUC congruency review and approval before the University will release funds associated with that award.
- Once the Pre-Review has been completed, the protocol will undergo IACUC Protocol Review Process as described, below.

✓ IACUC Protocol Review Process

The PHS Policy and AWRs recognize two methods of protocol review: Full Committee Review (FCR) and Designated Member Review (DMR). The following pertains to review of IACUC protocol submissions including, New, Annual Continuing Review (Progress Reports), as well as review of proposed Modifications (see table, below).

A member of the IACUC may not participate in the IACUC review or approval of an animal use protocol in which the member has direct or perceived conflict of interest except to provide information requested by the IACUC. A member of the IACUC who has a conflicting interest is recused from the meeting before deliberation on actions begin, is absent for the vote, and does not contribute to the quorum. The PI may also request that a member be excluded from the review of the protocol, provided there is evidence to substantiate the claim that a conflict of interest exists. In such cases, the IACUC, minus the member in question, will determine whether there is a conflict of interest according to the IACUC's Conflicts of Interest Policy.

The animal use protocols are reviewed by the IACUC through one of the two mechanisms:

Full Committee Review (FCR)

When FCR is recommended or requested, the PACS Administrator will convene a meeting with a quorum of IACUC committee members to review the protocol.

Designated Member Reviewer (DMR)

The PACS Administrator will provide copy of written protocol is to all IACUC committee members. During the allotted time window for committee comment, members are given opportunity to request its review under FCR, if they deem it necessary. If no requests for FCR are received, the IACUC Chair will appoint one qualified committee member to review the protocol

A complete description of FCR and DMR processes are provided below.

a. Full Committee Review (FCR):

When FCR is recommended or requested, the PACS Administrator will convene a meeting with a quorum of IACUC committee members to review the protocol. PACS will inform the PI, providing the date, time, and location of the meeting at which the protocol will be reviewed.

The IACUC follows a streaming process by which certain submissions will automatically require FCR. This determination is made by the AV during the vet consultation or pre-review process. The AV will indicate if the submission automatically requires FCR. One of three conditions will result in a submission automatically requiring FCR:

- 1. The submission is for use of mammals other than rats and mice (AWA covered species, such as hamsters, gerbils, etc.)
- 2. The submission involves major survival surgery in any species
- 3. The submission involves the withholding of pain relief (USDA pain category E) in any species

All members are given advance notice of the meeting.

A simple majority of the current members of the IACUC constitutes a quorum. If a quorum is lost at any time during the meeting, no further formal action will be taken until a quorum is attained. Any member who has a conflict of interest in a matter under consideration by the IACUC shall not be counted toward a quorum for that portion of the meeting. Any formal action taken by the IACUC (i.e., approval, suspension) must be approved by majority vote.

Submissions reviewed under FCR procedures are distributed to all members of the IACUC at least one week prior to the scheduled meeting. The IACUC typically meets once per month with additional meetings convened as necessary.

At least one member of the IACUC is assigned by the chair as primary reviewer for each protocol on the agenda. If the primary reviewer is unable to attend the convened meeting, he or she may provide his/her comments in writing to the committee. However, if the committee believes that the protocol cannot be given adequate and fair review due to absence of the primary and/or secondary reviewers, the review of the protocol is deferred until a future meeting. A mail ballot or individual telephone polling cannot substitute for participation in a convened meeting. Opinions of absent members that are transmitted by mail, telephone, fax or e-mail may be considered by the convened IACUC members but shall not be counted as votes.

PI is invited to attend by phone or in person to discuss his/her protocol with the IACUC. However, the PI will not be present during the IACUC's deliberations or vote.

IACUC meetings may be held partially or fully via telecommunications (e.g., telephone.) Documents normally provided to members during a physically convened meeting are provided to member(s) in advance of the meeting; all absent members must have access to the documents and the technology necessary to fully participate; a quorum of voting members is convened when required by PHS Policy; and the forum allows for real-time verbal interaction equivalent to that occurring in a physically convened meeting (i.e., members can actively and equally participate, and there is simultaneous communication). If a vote is called for, the vote occurs during the meeting and is taken in a manner that ensures an accurate count of the vote. Written minutes of meeting are maintained in accordance with the PHS Policy.

On rare occasions, the Committee may encounter major difficulty in making an assessment and an outside reviewer may be asked to consider the protocol. When it is determined that consultants or experts will be required to advise the IACUC in its review of a protocol, the protocol shall also be distributed to the consultants or experts prior to the meeting. The IACUC may invite consultants to assist in reviewing complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.

Although the committee strives for consensus, majority rule will apply. IACUC determinations, reached by the full committee, shall result in the protocol application (or other action) being assigned to one of the following determinations:

Approve

All review criteria per PHS policy, Animal Welfare Regulations, and University policies have been adequately addressed by investigator and approved to perform the experiments or procedures as described. PACS will issue the letter to the PI with a protocol number and approval and expiration dates. While protocols may be approved for up to maximum of three years. Continuing review is required on, at least, an annual basis.

Require Modifications to Secure Approval

Approval is withheld. The committee votes to require clarifications and/or minor modifications be made in order to secure approval. The PI will be notified in writing by PACS of the required clarifications and/or modifications.

Annually, at the beginning of each academic year, IACUC members sign a proxy agreeing that the members present at a convened meeting may vote to allow DMR subsequent to FCR when modification is required to secure approval as follows:

- At convened meetings of the IACUC, the Committee may vote to require modifications to secure approval and have the revised application either reviewed and approved by DMR, or returned for subsequent FCR.
- Amendments to approved protocols originally reviewed via FCR are automatically eligible for DMR.

If the Committee requires FCR for subsequent review, the submission will be placed on agenda of next IACUC meeting for review.

If Committee has voted for DMR for subsequent review, the submission will be sent to the DMR. DMR procedures (see below) are followed.

Once all clarifications and/or modifications have been made and all review criteria per PHS Policy, Animal Welfare Regulations, and University policies have been adequately addressed, the submission will be approved.

PACS will issue the letter to the investigator indicating the protocol approval period, and expiration date. Protocol approvals are valid for up to three years, continuing review is required on at least an annual basis.

Disapproved

IACUC determines that the submission has not adequately addressed all of the requirements of PHS policy, Animal Welfare Regulations, or University policies. This action may only be taken at full committee meeting review of the protocol. PACS will notify the PI in writing when a protocol is disapproved and will provide the basis for the IACUC's decision. When circumstances warrant, the chair, AVPR, or AV may call the PI to discuss the review. If a protocol is disapproved, the PI has the right of appeal to the IACUC. The IACUC may, at its discretion, obtain external review of the application by a PHS-approved IACUC of an equivalent institution and/or by expert consultants in the field of that research. The University at Albany IACUC, however, shall be the final authority in determining the acceptability of the protocol. A disapproval determination by the IACUC may not be overruled by any officer or employee.

Table (Defer until Future Meeting)

The IACUC may table a protocol if it requires substantial additional information and/or poses significant concern(s). PACS shall notify the PI in writing of the decision and will offer the PI an opportunity to discuss the protocol with the IACUC. Before IACUC review will continue, the PI must submit a revised protocol with the issues from the review addressed. There is no time limit on resubmission of a tabled protocol.

When FCR procedure is used, the approval date is the date that the submission receives final IACUC approval by the FCR or DMR (subsequent to FCR.)

b. <u>Designated Member Review (DMR):</u>

Using the DMR procedure, all IACUC members receive copies of protocol submission(s) and back up materials to be reviewed. If any member feels that a submission should go to the full committee for review, its review must be deferred to the next full IACUC meeting. Any member may make the request to send the application to FCR in the allotted time window (typically, 3-5 days) for committee comment.

If no member calls for FCR, at least one member of the IACUC, designated by the Chairperson and qualified to conduct the review, shall review the application and have the authority to approve, require modifications in (to secure approval) or request full committee review of the application.

DMR reviewers do not have the authority to withhold approval; in such cases the application is submitted for FCR. DMR approval has equal validity to full-committee review approval and does not require subsequent re- approval or notification at a convened meeting. It is always possible for the IACUC to discuss applications approved by either method in future meetings as a form of continuing review or in response to animal welfare concerns.

If a protocol is assigned more than one designated reviewer, the reviewers must be unanimous in any decision. They must review identical versions of the protocol and if modifications are requested by any one of the reviewers then the other reviewers must be aware of and agree to the modifications.

In cases where committee members are also investigators on the protocol, the member will recuse him/herself from the deliberation and vote. The chair will designate another IACUC member to do the review. When the chair is absent or is PI or co-PI on the protocol, the chair's designee will accomplish or assign the review.

IACUC determinations, reached by the DMR, shall result in the protocol application (or other action) being assigned to one of the following determinations:

Approve

All review criteria per PHS Policy, Animal Welfare Regulations, and University policies have been adequately addressed by investigator and approved to perform the experiments or procedures as described. PACS will issue the letter to the investigator indicating the protocol approval period, and expiration date. While approvals are valid for up to three years, continuing review is required on at least an annual basis.

Require Modifications to Secure Approval

The DMR reviews the protocol to ensure compliance with applicable regulations and policies, and will request clarification or pose questions to the investigator when need for such clarification exists. The PI will be notified in writing by PACS of the required clarifications and/or modifications. Once clarifications and/or modifications have been made by the investigator and all review criteria per PHS Policy, Animal Welfare Regulations, and University policies have been adequately addressed, the DMR either approves the submission or refers the protocol to FCR for Review. If approved, PACS will issue the letter to the investigator indicating the protocol approval period, and expiration date. Protocol approvals are valid for up to three years, continuing review is required on at least an annual basis.

Referral to the Full Committee for Review

When the DMR refers a protocol to FCR, PACS will inform the investigator of this referral and will provide the investigator with the date, time, and location of the meeting at which the protocol will be reviewed.

When DMR procedure is used, the approval date is the date that the submission receives final IACUC approval by the DMR.

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.

Proposed modifications must be submitted to the IACUC via a Modification Request Form. PI's may not implement any modifications to approved protocols until such modifications have been approved by the IACUC.

Significant modifications must be reviewed and approved by one of the valid IACUC approval methods described above; that is, FCR or DMR and minor modifications are reviewed and approved "Administratively" by the Chair, Attending Vet or PACS Administrator. Please see table, on next page.

Investigators are informed of the decision in writing. The IACUC minutes contain notification of all actions approved as "Minor," "Significant," or "Administrative" modifications.

	SIGNIFICANT	MINOR MODIFICATION		
PROPOSED CHANGE	MODIFICATION	ADMINISTRATIVE		
THOI OSED CHANGE	IACUC DMR OR FCR	CHAIR OR ATTENDING VET	PACS	
New procedure	X			
Increase in number of animals over approved number	x			
Change in study objectives	Addition of new aims that are not extensions of existing aims		Addition of new aims that are extensions of existing aims (with agreement of IACUC Chair)	
Grant			Addition of new grant already on the protocol (with assurance of protocol-grant congruency by the PI and verification by PACS)	
Change in housing and/or use of animals in location that is not part of the animal program overseen by IACUC	X			
Change in species, additional of new species, or change in strain	Change or addition of new species or addition of strain that is more susceptible to pain or discomfort	Addition or change in strain of approved species that is equivalent in susceptibility to pain or discomfort		
Duration, frequency, or number of procedures performed on an animal	Х			
Anesthesia, analgesia, sedation or withholding of analgesics	x			
Significant food/water restriction (not routine fasting)	x			
Change from non-survival to survival surgery	x			
Change from survival to non-survival surgery		х		
Changes in dose volume or route of experimental materials	x			
Changes in euthanasia or euthanasia method	x			
Change that would require animals to be fed, housed or cared for in any way that is not standard for that species, or does not meet that species' minimum requirements	x			
Changes that would impact personnel safety	x			

	SIGNIFICANT	MINOR MODIFICATION	
PROPOSED CHANGE	MODIFICATION	ADMINISTRATIVE	
PROFOSED CHANGE	IACUC DMR OR FCR	CHAIR OR	PACS
Change in study personnel	Change of PI	ATTENDING VET	Change in personnel other than PI (after verification that personnel are trained, qualified and enrolled in Occupational Health & Safety programs)
Administrative (typographical, grammar, contact information)			X

- 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 a determination is made by the IACUC regarding an activity, PACS prepares a letter that is sent to the PI on behalf of the IACUC. When circumstances warrant, the Chair, AV, or AVPR may contact the PI to discuss a determination (this is more likely with a determination to table or disapprove.) A record of such actions is made in the next IACUC meeting's agenda, which is distributed to all IACUC members.
- 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. The protocol approval letter states that in accordance with the PHS/USDA/APHIS regulations investigators must submit an annual report on the progress of their project unless the IACUC has requested it be submitted sooner and a new protocol application must be submitted at the end of three years. The protocol will be reviewed following the IACUC procedures for protocol review as described above in Section III.D.6.
 - B. Post-approval monitoring (PAM) for animal protocols is aimed at improving the communication between animal researchers, the IACUC, and PACS, and preparing the animal program for the inspections performed by the USDA (United States Department of Agriculture), and the PHS (Public Health Service). The PAM program will primarily center on a dialogue between the investigators and the PACS staff. During the visit, PACS staff will ask the PI and the laboratory staff that are present to verbally describe their animal procedures. PACS staff will assist the investigator in identifying any inconsistencies and concerns by comparing these verbal reports to the approved animal use protocol. The visit will also involve review of associated study records including monitoring records, animal use records, etc., to help ensure that all procedures being conducted are included in the protocol. Because junior faculty, trainees and professional research assistants are often the ones performing the procedures, the PI is encouraged to invite the personnel affiliated with the protocol to participate in the meeting. Specific objectives of the PAM system are:
 - To cooperatively compare the approved procedures and the day-to-day work, and correct any discrepancies to the protocol so that it will comply with PHS and USDA regulations;

- To communicate to the researchers any changes in the PHS and USDA regulations, as well as IACUC policies;
- To communicate to the IACUC any ongoing problems with animal husbandry, facility
 operations, and program personnel related to the work that is approved in the protocol.
- 10- The IACUC is authorized to suspend an ongoing activity that is not being conducted in accordance with the *Guide*, Animal Welfare Act, PHS policy, New York State law, University at Albany Assurance, requirements of funding agency, or that has been associated with unexpected serious harm to animals subjects.

The IACUC may suspend an activity only after review of the matter at a convened meeting of the IACUC, and with the affirmative vote of a majority of the quorum present. If the IACUC suspends an activity, the Committee shall document the action, describing the reasons for the IACUC's action.

In such an event, the AVPR will promptly notify the investigator in writing of the Committee's decision to suspend approval of any given activity related to the care and use of animals.

The AVPR will have the additional responsibility of notifying, in writing, the AV, LAR, IO, appropriate oversight agencies, and other appropriate university offices (e.g., Awards Management Services, etc.), and include the reasons for the suspension, any applicable corrective action(s) and any further action(s) anticipated. In such an event, the AVPR is to seek follow-up confirmation that the suspension has been specifically noted by each of the administrative officials listed.

Investigators will have fifteen (15) business days from receipt of the suspension or termination statement to submit a written appeal to the IACUC. The appeal will not act to stay the decision to suspend or terminate the activity. If no appeal is made, the decision will stand as final. The IO or his/her designee, in consultation with the IACUC, will take the following actions:

- a. review the reasons for suspension,
- b. take appropriate remedial action and
- c. report the corrective action to any sponsor funding that activity.

A full committee review will be held within fifteen (15) business days of all appeal requests. The investigator will have the opportunity to meet with the committee and individuals with expertise on the subject or outside consultants may be called to aid in the appeal decision. The committee will issue a final decision within fifteen business days.

A written report will be presented to the IO within one week of such a meeting, and a copy of this report will be forwarded to OLAW. The IO will forward a full explanation of the incident and resulting action to OLAW, other funding agencies and the USDA as required.

Exception: The AV has the authority to immediately halt an ongoing activity that does not follow the *Guide*, Animal Welfare Act, PHS policy, New York State law, University at Albany Assurance, or requirements of funding agency.

The AV sits as a voting member of the IACUC. The AV is additionally charged to make his/her own unannounced inspections of our facilities, husbandry procedures and other animal-related activities. The AV has the authority to immediately halt an ongoing activity that s/he deems unacceptable based on animal welfare considerations. In the event that the AV exercises this separate authority to halt any given activity, s/he will immediately notify the Investigator via a written notification of the halt.

The AV will also notify all of the following individuals: the investigator, the IACUC Chair, the IACUC, the LAR facilities manager, the IO, and the AVPR and will follow up with a written report within 24 hours. The AV is to seek follow-up confirmation that the halt has been specifically noted by each of the university personnel listed above.

The IACUC Chair will convene a meeting of the full IACUC membership within 7 business days of any such halt by the AV. At this meeting, the IACUC membership will review the matter, hearing from all concerned parties, and then determine whether the animal-use protocol in question will be permitted to resume or if IACUC suspension is warranted. The IACUC will vote to permit activity to resume or for suspension of the activity only after review of the matter at a convened meeting and with the affirmative vote of a majority of the quorum present. The IACUC shall document the action taken, describing the reasons for the IACUC's action...

The AVPR will promptly notify the investigator in writing of the Committee's decision.

A written report will be presented to the IO within one week of such a meeting, and a copy of this report will be forwarded to OLAW. The IO will forward a full explanation of the incident and resulting action to OLAW, other funding agencies and the USDA as required.

E. Occupational Health and Safety Program (OHSP)

All individuals listed on an active approved animal use protocol must participate in the OHSP. The OHSP consists of two parts: an online training module provided through AALAS and a health and risk assessment form.

- 1- The <u>online training</u> is provided through the American Association for Laboratory Animal Science (AALAS) Learning Library. The University at Albany AALAS Occupational Health and Safety Course for Research Animal Users covers topics such as:
 - Animal Welfare Regulations;
 - Physical, chemical, and protocol-related hazards;
 - Allergens;
 - Zoonosis;
 - Safe work practices.
 - Special areas of concern, such as pregnancy, illness, or compromised immune status

Each lesson must be opened and the final exam passed in order to satisfy this part of the OHSP training requirement.

- 2- The health and risk assessment element of the program is risk-based with recommendations to individuals based upon: hazards posed by animals; materials used; exposure intensity, duration, and frequency; personnel susceptibility; and history of occupational illness and injury. The Institution has contracted with Community Care Physicians (CCP) to provide the assessment. The medical health and risk assessment form is completed by all personnel working in laboratory animal facilities or as key personnel in an animal use protocol. The completed form is reviewed by a CCP physician. The physician will identify personnel with allergies, pregnancy, immunocompromised status, or other pre-existing conditions; determine baseline health status for future comparisons; determine tetanus vaccine history and offer vaccination when necessary. The individual and principal investigator will be notified by e-mail if the applicant is medically cleared for the assignment proposed or if the applicant is required to schedule a physical exam with the health care provider at CCP. If physical exam is required, after the exam, the CCP physician will complete a written medical opinion, stating whether the examinee has any limitations, including respirator use where applicable. The medical health and risk assessment form is available on the LAR website and must be completed annually.
- 3- LAR also provides a <u>training program for animal users</u> working in campus animal facilities. The program includes training on personal protective equipment (PPE), safety eyewash usage, minimizing injuries, bite wounds, disaster planning and other safety topics. Animal users, as appropriate, are instructed on proper animal care and use, handling and restraint, injections, and blood extraction techniques. These training courses will be performed by the LAR facilities manager or other trained animal care personnel. Upon LAR request, Environmental Health & Safety (EH&S) will provide training in chemical safety, sharps, hazardous waste disposal, fire safety, and lab safety, specific to the animal facility. On-the-job injuries, such as bites and scratches, are also handled by EH&S. The employee is instructed to fill out an

accident report, which is sent to EH&S, the employee's supervisor, and HR. The employee is encouraged to seek medical attention immediately at urgent care, or in the case of students, Student Health Services.

- 4- Personal protective equipment such as laboratory coats, boots, gloves and masks is available for all animal care workers. Eye protection and face shields are provided for working with acids or other hazardous chemicals or biological agents that may splash.
- 5- Appropriate personnel from the EH&S will also review protocols, as necessary, if hazardous agents (e.g., radioactive materials) are involved. As required, all necessary training and follow-up will be provided by EH&S staff.
- 6- The University does not use non-human primates currently and does not have plans to use or house them in the future.

F. Third-Party Agreements

The AVPR is responsible for ensuring that any arrangement for the care or use of live vertebrate animals in the facilities of another organization, whether by that organization's employees or University personnel, which is provided by or through the University, will be carried out in accordance with this Assurance. Thus:

For protocols which include transfer to a third party, by contracting or any other means, the actual performance of substantive programmatic work involving the use of live vertebrate animals, the AVPR shall require evidence from the proposed third-party performer that it has an approved Assurance on file with OLAW and that the protocol in question has been approved by that organization's IACUC, or an Interinstitutional Agreement will be negotiated between the University and the external third-party performers and that such Interinstitutional Assurance will be submitted to OLAW for approval prior to the conduct of any animal use.

G. Facilities and Species Inventory

The total gross number of square feet in each animal facility and the average daily inventory by species, of animals in each facility is provided (see Part X.)

H. Training and Instruction of Personnel Involved with Animals

The University at Albany has mandatory education in the ethical principles and guidelines for the use of animals in research. The educational requirement applies to all University at Albany researchers and key personnel involved in research using animals, whether the research is funded or unfunded. IACUC members, LAR staff, and PACS staff are also required to complete the training. The University at Albany offers the CITI Laboratory Animal Welfare Courses to fulfill the University's Laboratory Animal Welfare education requirement. Training and reference materials are also accessible through the Institution's AAALAS Learning Library account.

In order to be able to conduct research involving use of laboratory animals, all personnel must have:

- Current successful completion of CITI training certification (or equivalent);
- Current successful completion of the OHSP;
- Successful completion of facility orientation and training;
- Successful demonstrated proficiency in the handling and care of laboratory animals;
- Technical education is based upon individual need and species used including:
 - proper handling and care;
 - resources available for animal users provided by the University;
 - pre-and post-surgical care;

- proper use of anesthetics, tranquilizers and pain relieving drugs;
- aseptic surgical procedures.

In addition, training sessions may be offered periodically on various topics such as:

- 1) State and federal regulations, principles, policies and laws related to animal use and
- weltare;

 Public interest issues including humane treatment of animals and the ethics of animal
- use in research and education;

 3) Institutional responsibilities in animal use including the function of the IACUC;
- 4) Responsibilities of individual investigators, educators, laboratory technicians, animal care
- personnel and students assuring proper animal care and welfare;

 5) How and to whom animal care deficiencies and concerns can and should be reported;

 (2)
- 6) Research and testing methods that minimize the number of animals required to obtain
- valid results and limit animal pain or distress.

 7) Resources available for reducing the number of animals used;
- 8) Resources available for further training at the University of Albany;
- 9) Such items as the IACUC shall deem necessary.

Principal investigators and key personnel must provide sufficient proof of qualifications for animal use to the IACUC, the LAR facilities manager, or the attending Veterinarian (for invasive procedures) prior to beginning animal use. Any investigator lacking sufficient qualifications will be provided with appropriate training from any of the following:

- ★ the LAR facilities manager;
- the attending veterinarian;
- ★ the LAR animal care staff.

All animal care staff and users are encouraged to seek continuing education throughout their employment at the University at Albany. Training opportunities, when offered, (e.g., offerings by PRIM&R, AAALAS, etc.) are made available by the University. Documentation of all individuals trained for animal use is maintained with the IACUC records.

Upon appointment to the committee, IACUC members are provided with an orientation, background materials, resources and training. Members are provided with a copy of the PHS Policy, the Guide, the Arena/OLAW IACUC Guidebook, and a copy of the University at Albany approved Animal Welfare Assurance. Training opportunities, when offered, (e.g., offerings by PRIM&R, AAALAS, etc.) are made available by the University. 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 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 made available to the OLAW upon request.

This Institution is Category 2 — not accredited by the <u>Association for Assessment and Accreditation of Laboratory</u>

Animal Care International (AAALAC)

Anima

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.
 - 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.

V. 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.
 - 5. Any minority views filed by members of the IACUC
- 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.

VI. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: James A. Dias, Ph.D	
Title: Vice President for Research	
Name of Institution: State University of New York - U	University at Albany
Address: (street, city, state, country, postal code)	
1400 Washington Ave, UNH 307 Albany, NY 12222	
Phone: 518-956-8170	Fax: 518-956-8175
E-mail: rco@albany.edu	
Acting officially in an authorized capacity on behalf of Institution's responsibilities under this Assurance, I above.	of this Institution and with an understanding of the assure the humane care and use of animals as specified
Signature:	Date:
Jeimo allias	6/30/16
Dr. Venita B. Thornton - Senior Assurance Offic Office of Laboratory Animal Welfare National Institutes of Health 6705 Rockledge Drive RKL1, Suite 360, MSC 7982 Bethesda, MD 20892-7982	
Venita B Thomaton pun,	Date: 7/a6/2016
Assurance Number: A-3621-01	
Effective Date: Out ab 20/6	Expiration Date: 0,1,1,31,2020

^{****} PHS Policy Membership Requirements:

Veterinarian	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

[Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.]

VIII. Other Key Contacts

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

be considered nonaffiliated.

Contact #1						
Name:	Adrienne D. Bonilla, Esq.					
Title:	Assistant Vice President for Research & Director PACS					
Phone:	E-mail: abonilla@albany.edu					
Contact #2						
Name:	Name:					
Title:						
Phone: E-mail:						

^{*} This information is mandatory.

^{**} 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").

IX. Facility and Species Inventory

Date: 6/24/16							
Name of Institution: State University of New York - University at Albany							
Assurance Number:	A3621-01						
Laboratory, Unit, or Building [*]	Gross Square Feet [include service areas]	Species Housed [use common names, e.g., mouse, rat, rhesus, baboon, zebra fish, African clawed frog]	Approximate Average Daily Inventory				
MC	23,000	Mouse	930				
MC	23,000	Rat	150				
EC	10,000	Mouse	450				
EC	10,000	Rat	240				
MC-BIO-1	350	Zebra Fish	0				
MC-BIO-2	325	African Clawed Frog	30				
MC-BIO-2	325	Western Clawed Frog	35				

^{*}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.

VII. Membership of the IACUC

Chairperson Name, Title, and Degree/Credentials	Business Address, Phone, Fax, and Email of Chairperson			
Name: Brian Parr	Address: East Campus CRC 342B 1 Discovery Drive Rensselaer NY 12144-3456			
Title: Principal Research Scientist				
Degree/credentials: Ph.D. Evolutional Biology	Phone: 51	18-591-7213	Fax:	Email: bparr@albany.edu

Name of Member/Code*	Degree/ Credentials	Area of Study	Position Title***	PHS Policy Membership Requirements**
Antigone McKenna	DVM	Veterinary Medicine	Veterinarian/LAR director	Attending Veterinarian
Nayan Gosai	B.S.	Biology	Hazardous Waste Specialist & Chemical Hygiene Officer	Scientist
William Carpenter	M.S.	Rehabilitation Counseling	NYS Office of Alcoholism and Substance Abuse Services, Addictions Program Specialist	Non-Scientist / Non-Affiliated
Magnus Bergkvist	Ph.D.	Surface Biotechnology	Assistant Professor	Scientist
Donald Orokos	Ph.D.	Cell Biology	Adjunct Assistant Professor	Scientist



MEMORANDUM

TO:

James Dias

Vice President for Research

FROM:

Adrienne D. Bonilla, on behalf of

Institutional Animal Care and Use Committee (IACUC)

DATE:

March 31, 2016

RE:

IACUC Semi-Annual Report

This report constitutes the semiannual evaluation of the University at Albany's laboratory animal care and use program by the Institutional Animal Care and Use Committee (IACUC).

Semi-Annual Report to VPR Animal Program Reporting Period: Sep 01, 2015 – Feb 29, 2016

SUMMARY

Semi-Animal Facility Inspection – EC	10/28/2015	
Semi-Animal Facility Inspection MC	10/29/2015	
Semi-Annual Program Review	11/19/2015	

With regard to the semi-annual program review of the University's animal care and use program, overall, the Committee found the program to be in compliance.

With respect to the semi-annual facility inspections, inspected areas were observed to be in compliance.

The facility inspection reports and program review reports are attached.



IACUC SEMIANNUAL FACILITY INSPECTION REPORT

Instructions for Inspectors:

- 1. Inspect each area using the criteria listed in each section below.
- 2. Identify the room number for which you would like to enter a comment.
- 3. For each room number selected, indicate one of the following choices:
 - A Acceptable
 - M Minor deficiency
 - S Significant deficiency (is or may be a threat to animal health or safety),
 - SFI Suggestion For Improvement
- 4. Enter the required timeline for corrective action, if a deficiency is identified.

5. Enter a comment with sufficient detail to inform the facility manager and the IACUC of the issue	and the
specific corrective action required.	

opeonie con court action required.						
DATE OF INSPECTION:	10/28/2015	9:00 AM	Main Campus	☐ East Campus	\boxtimes	
INSPECTOR:	Brian Parr,	William Carp	enter			

Animal Housing Areas

Animal Housing and Support Areas

(animal condition, appropriate food and water, separation by species, separation by disease status, exercise, behavioral management, animal records present, lighting acceptable, temp/humidity logs, ventilation/air exchanges, clean cages/ racks, proper waste disposal, proper use of hazardous agents, surfaces easily sanitized, room clean and neat, proper no. of animals/cage, animal equipment clean, weather protection, bedding, NYSDOH certificate posted)

Room No.	Α	М	S	SFI	2wks	4wks	Other	Comments
CRC B09	Х							Releine Lab – Mouse in vent rack
CRC B11	Х							Conklin Lab – Mouse
CRC B13	Х						· · · · · · · · · · · · · · · · · · ·	Conklin Lab – Mouse
CRC B21	Х							Temple Lab - Mouse
CRC B23	Х							Welsh/Parr/ Begley & Endres - Mouse
CRC B25	Х							Temple Lab – Rat

IACUC Semi-Annual Facility Inspection East Campus: October 28 and Uptown: October 29,2015 -Page 1 of 13

Animal Housing and Support Areas

(animal condition, appropriate food and water, separation by species, separation by disease status, exercise, behavioral management, animal records present, lighting acceptable, temp/humidity logs, ventilation/air exchanges, clean cages/ racks, proper waste disposal, proper use of hazardous agents, surfaces easily sanitized, room clean and neat, proper no. of animals/cage, animal equipment clean, weather protection, bedding, NYSDOH certificate posted)

Room No.	Α	M	S	SFI	2wks	4wks	Other	Comments
CRC B36	Х							Storage
CRC B31	Х							Drug room

Food Storage Areas

(type and distribution, expiration date labeling, rotation of stocks, storage in sealed containers, quality control, located off the floor and away from the walls)

Room No.	Α	M	S	SFI	2wks	4wks	Other	Comments
CRC B34	Χ							Storage

Bedding Storage Space

(type and use, storage)

(type and dee,	0.0.	<u> </u>					
Room No.	Α	М	S	SFI	2wks	4wks	Other Comments
CRC B24	Х						
CRC B22	Х						

Water Source

(treatment and distribution, quality control)

La cadilloni and	<i>a</i> 0.00		o.,, que	,				
Room No.	Α	M	S	SFI	2wks	4wks	Other	Comments
CRC B15	Х							Cage wash – clean side

Cleaning and Sanitation

(cages, feeders, water distribution system, room, general facility, waste disposal [storage, hazardous wastes, carcasses])

Room No.	Α	М	S	SFI	2wks	4wks	Other	Comments
CRC B16	Х							Cage wash – dirty side

Personnel

(SOP's, protocols [available, number posted], designated area, emergency, weekend and holiday)

OO, 0, p. 0.0.		A 1 OIIIO	~,		p	accignated and an entropy of the control and t				
Room No.	Α	M	S	SFI	2wks	4wks	Other	Comments		
CRC B09	Х							Releine Lab		
CRC B11	х							Conklin Lab		
CRC B13	Х							Conklin Lab		
CRC B21	Х							Temple Lab		
CRC B23	Х							Welsh/Parr/ Begley & Endres		
CRC B25	Х							Temple Lab		

Occupational Health and Safety

(personal protective equipment)

Room No.	Α	M	S	SFI	2wks	4wks	Other	Comments
CRC B14C	X.							

Infrastructure/Construction

(security, walls, floors, ceilings, doors, HVAC, power and lighting, drainage)

Room No.	Α	M	S	SFI	2wks	4wks	Other	Comments	
CRC B21	Х								

Specialized Space

(receiving, quarantine/isolation, necropsy, diet preparation, imaging, surgery, procedure, cage wash, carcass disposal)

Room No.	Α	M	S	SFI	2wks	4wks	Other	Comments
CRC B29	Х							Quarantine area - vacant
CRC B20	Х							Euthanasia / Procedure Room
CRC B18	Х							Necropsy Freezer
CRC B16	Х							Cage wash- Clean side
CRC B16	Х							Cage wash- Dirty side
CRC B12B	Х							Receiving area

Procedure Rooms

General

(drug storage, control and expiration dates, sharps disposal (SOP), anesthetic monitoring, gas cylinders immobilized, Appropriate hazard signs, carcass disposal, transport of animals to and from animal housing, length of time in procedure room, NYSDOH certificate posted)

Room No.	Α	М	S	SFI	2wks	4wks	Other	Comments
CRC B30	Х							Parr Lab
CRC B26	Х							Temple Lab – Surgery room
CRC B19	Х							Temple Lab – Surgery room
CRC B17	Х							Welsh / Conklin/ Begley lab
CRC B12A	Х							LAR staff use
CRC 111	Х							Neural Stem Cell Institute
CRC 113	Х							Neural Stem Cell Institute
CRC 115	Х							Neural Stem Cell Institute
CRC 120	Х							Neural Stem Cell Institute

Additional Concerns for Survival Surgery (rodent or minor procedures only --- rodent survival surgery clean and uncluttered, not used for anything else during surgery)

Room No.	Α	М	s	2wks	4wks	Other	Comments
CRC B30	Х		i				
CRC B19	X						
CRC B17	Х						

IACUC Semi-Annual Facility Inspection East Campus: October 28 and Uptown: October 29,2015 -Page 3 of 13

Animal Housing and Support Areas – Aquatic Specific UNIVERSITYATALBANY State University of New York

(standards for acceptable quality are established, chlorine, chloramines, chemical, and reactive bioproducts are removed or neutralized prior to use in aquatic systems, primary enclosure provides a balanced, stable environment Construction allows undisturbed observation and with nontoxic materials, prevents electrical hazards, environment enrichment elicits appropriate behaviors and is safe semi-aquatic reptiles are provided terrestrial areas, nets are cleaned, disinfected and managed to avoid contamination of systems, water quality parameters and frequency of testing recorded, records kept on feeding, non-expired food supplies, live cultures, frequency of tank/cage cleaning and disinfection is determined by water quality, permits adequate viewing and health monitoring

	oom No.	Α	М	S	SFI	2wks	4wks	Other	Comments
ı	NA								** NO AQUATIC ANIMALS IN EAST CAPUS **

REPORT SUMMARY

Note: Please check the box above ONLY if no data has been entered on the inspection form.

Notes/comments No deficiencies – all rooms are set up and used appropriate manner

Administrative Notes:

- ** Information sheet of Lab on animal housing door (include Personnel/contact information and protocol numbers) need to be updated by the Facility.
- ** Report of concern and contact information to the ORRC need to be posted in the common area.

IACUC Semi-Annual Facility Inspection East Campus: October 28 and Uptown: October 29,2015 -Page 4 of 13

REPORT SUMMARY

П	We have inspect	ed all the listed roor	ns and found no defi	ciencies.							
Note: P	lease check the box	above ONLY if no data	has been entered on the	inspection form.							
		Deficien	cies								
> For each	> For each deficiency identified, specify the "correct by date."										
	LAR is responsible for addressing all deficiencies (significant and minor) within the timeframe required by the IACUC, and informing the IACUC (via ORRC) of the final resolution.										
When Suggestions for Improvement are made, LAR must address whether or not the suggestions were incorporated.											
Significant deficiencies that are not corrected within the required timeframe must be reported to the appropriate regulatory agency.											
Room No.	o. Acceptable Minor deficiencies Significant Suggestions For deficiencies Improvements										
Commenda	Commendations:										
Notes/comments:											
Signatu	re: All subcomm	ittee members cond	ucting this inspection	n must sign below.							
Print Brian Pa			gnature Bin	Pan							
Print Magnus	: Bergkvist	Sig	gnature								

IACUC Semi-Annual Facility Inspection East Campus: October 28,2015 -Page 5 of 5

REPORT SUMMARY

☐ We have inspected all the listed rooms and found no deficiencies.											
Note: I	Note: Please check the box above ONLY if no data has been entered on the inspection form.										
		Deficienc	cies								
> For (each deficiency ident	ified, specify the "correct	by date."								
➤ LAR is responsible for addressing all deficiencies (significant and minor) within the timeframe required by the IACUC, and informing the IACUC (via ORRC) of the final resolution.											
	n Suggestions for Im incorporated.	provement are made, LA	R must address whether	or not the suggestions							
	ificant deficiencies the opriate regulatory ag	nat are not corrected within ency.	n the required timeframe	must be reported to the							
Room No.	Acceptable	Minor deficiencies	Significant deficiencies	Suggestions For Improvements							
ommend		-									
otes/con	nments:										
Signat	ure: All subcomn	nittee members condu	ucting this inspectior	n must sign below.							
rint Bri an F	Parr	Sig	nature	4							
rint Magn ı	us Bergkvist Willi	am Carpentersig	nature Will His								

IACUC Semi-Annual Facility Inspection East Campus: October 28,2015 -Page ${\bf 5}$ of ${\bf 5}$

IACUC SEMIANNUAL FACILITY INSPECTION REPORT

Instructions for Inspectors:

- 1. Inspect each area using the criteria listed in each section below.
- 2. Identify the room number for which you would like to enter a comment.
- 3. For each room number selected, indicate one of the following choices:
 - A Acceptable
 - M Minor deficiency
 - S Significant deficiency (is or may be a threat to animal health or safety),
 - **SFI** Suggestion For Improvement
- 4. Enter the required timeline for corrective action, if a deficiency is identified.

5. Enter a comment	t with sufficient detail t	to inform the facility	manager and th	ne IACUC of the	issue and the
specific corrective a	action required.				

specific corrective action req		and received manager and		
DATE OF INSPECTION: Inspector :	October 29, 2015 Donald Orokos, N	_	East Campus	

Animal Housing Areas

Animal Housing and Support Areas

(animal condition, appropriate food and water, separation by species, separation by disease status, exercise, behavioral management, animal records present, lighting acceptable, temp/humidity logs, ventilation/air exchanges, clean cages/ racks, proper waste disposal, proper use of hazardous agents, surfaces easily sanitized, room clean and neat, proper no. of animals/cage, animal equipment clean, weather protection, bedding, NYSDOH certificate posted)

Room No.	Α	M	S	SFI	2wks	4wks	Comments
LSRB 052	х						Zuloaga Lab
LSRB 061	х						Workman Lab
LSRB 060		х					Poulos Lab - Rats Protocol # error on cage card (Responsible Party: Investigator)*
LSRB 056	х						Wagner Lab - Rat
LSRB 058	х						Poulos Lab – Mice; The number of animals noted on the card did not match the number of animals inside of the cage. Newly born animals (DOB = 10/28/15) were missing bedding. (Responsible Party: Facility) **
LSRB 057	х						Forni Lab
LSRB 059	х						Wagner Lab - Mice
LSRB 048		х					Larsen Lab The protocol numbers posted on the doors do not match the protocol numbers listed on the cages. (Responsible Party: Facility) **

IACUC Semi-Annual Facility Inspection East Campus: October 28 and Uptown: October 29,2015 -Page 5 of 13

Room No.	Α	М	S	SFI	2wks	4wks	Comments
LSRB 053		x		х			Chen Lab — Mice ** NO LAB CONTACT INFORMATION
		^		^			The signage on the door was missing. (Responsible Party: Facility) **
LSRB 049		x					Scimemi Lab Chemical abbreviations are not permitted. Two bottles of ethanol were labeled as 70% ETOH on the countertop. A bottle was labeled as dH20. A bottle was labeled as PBS. (Responsible Party: Investigator)*

Food Storage Areas (type and distribution, expiration date labeling, rotation of stocks, storage in sealed containers, quality control, located off the floor and away from the walls)

Room No		Α	M	S	SFI	2wks	4wks	Comments
LSRB B004	-	Χ	·				<u> </u>	

Redding Storage Space (type and use storage)

Room No.	Α	M	S	SFI	2wks	4wks	Comments
LSRB B044	х						*Room locate at animal housing area Flammables are not permitted to be stored in a regular refrigerator due to an explosion hazard. Chemical abbreviations are not permitted. Two tubes were labeled as ETOH and being improperly stored in a regular refrigerator. This is a fire safety violation. (Responsible Party: Facility) **

Water Source (treatment and distribution, quality control)

Room No.	Α	M	S	SFI	2wks	4wks	Comments
LSRB B042		х		x			Cage wash, clean side All containers must be properly labeled. The white (possibly empty) carboy next to the Quadracide container was missing a label. It was mentioned that the cleaning system is not functional or is not being used. If so, containers from this system should be disposed of accordingly. (Responsible Party: Facility) **
LSRB B043		X					Cage wash, dirty side Eye wash is not being tested weekly and the last annual inspection was conducted on 11/1/13. (Responsible Party: Facility) **

Cleaning and Sanitation (cages, feeders, water distribution system, room, general facility, waste disposal [storage, hazardous wastes, carcasses])

Room No.	Α	М	S	SFI	2wks	4wks	Comments
LSRB B042		х		x			Cage wash, clean side All containers must be properly labeled. The white (possibly empty) carboy next to the Quadracide container was missing a label. It was mentioned that the cleaning

IACUC Semi-Annual Facility Inspection East Campus: October 28 and Uptown: October 29,2015 - Page 6 of 13

		system is not functional or is not being used. If so, containers from this system should be disposed of accordingly. (Responsible Party: Facility) **
LSRB B043	х	Cage wash, dirty side Eye wash is not being tested weekly and the last annual inspection was conducted on 11/1/13. (Responsible Party: Facility) **

Personnel (SOP's, protocols [available, number posted], designated area, emergency, weekend and holiday)

Room No.	Α	М	S	SFI	2wks	4wks	Comments
LSRB 052	Х						Zuloaga Lab
LSRB 061	Х						Workman Lab
LSRB 060		х		х			Poulos Lab - Rats The protocol numbers posted on the door do not match the protocol numbers listed on the cages. (Responsible Party: Facility) **
LSRB 056	Х						Wagner Lab - Rat
LSRB 058	Х						Poulos Lab – Mice
LSRB 057	Х						Forni Lab
LSRB 059	Х						Wagner Lab - Mice
LSRB 048		х		х			Larsen Lab The protocol numbers posted on the doors do not match the protocol numbers listed on the cages. Suggest updating the labeling system. (Responsible Party: Facility) **
LSRB 053		х	!	х			Chen Lab – Mice ** NO LAB CONTACT INFORMATION (Responsible Party: Facility) **
LSRB 049	х						Scimemi Lab

Infrastructure/Construction (security, walls, floors, ceilings, doors, HVAC, power and lighting, drainage)

Room No.	Α	M	S	SFI	2wks	4wks	Comments
LSRB B066	Х						Storage
LSRB B050	Х						Storage
LSRB B051	Х						Storage
LSRB B054	Х						Storage
LSRB B063	Х						Schimemi Lab Procedure Room
LSRB B064	Х						Storage
LSRB B065	Х						Storage

Occupational Health and Safety (personal protective equipment)

Room No.	Α	M	S	SFI	2wks	4wks	Comments
LSRB B007	Х						Changing room

Specialized Space (receiving, quarantine/isolation, necropsy, diet preparation, imaging, surgery, procedure, cage wash, carcass disposal)

IACUC Semi-Annual Facility Inspection East Campus: October 28 and Uptown: October 29,2015 -Page 7 of 13

Room No.	Α	M	S	SFI	2wks	4wks	Comments
LSRB BO40		x					Necropsy Room Hazardous waste should be disposed of on a regular basis. The cabinets under the hood contained an excessive amount of hazardous waste. (Responsible Party: Facility) ** The Spill-X-FP for formaldehyde spills is no longer usable and should be replaced with a new one. All containers must be properly labeled. Two carboys were labeled with the PI's (McNay) name. (Responsible Party: Investigator)* Chemical abbreviations are not permitted. A bottle of ethanol was labeled as 70% ETOH. A bottle was labeled as 0.9% NaCl in the refrigerator. A bottle was labeled as PBS, also in the refrigerator. (Responsible Party: Facility) ** (Responsible Party: Investigator)*
LSRB B003	Х						Receiving Room
LSRB B032	Х						Euthanasia room
LSRB B055	х						Quarantine Area

Additional Concerns for Survival Surgery

(rodent or minor procedures only --- rodent survival surgery clean and uncluttered, not used for anything else during

surgery)

Room No.	Α	M	S	SFI	2wks	4wks	Comments
LSRB B039A		х					Surgery Room The floor drain for the auto-clave is corroding and should be cleaned/replaced. All containers must be properly labeled. Two containers (possibly empty) under the sink were missing labels. (Responsible Party: Facility) **
LSRB B067	х		:		i		Recovery
LSRB B041	Х						New Surgery Room

Procedure Rooms

General(drug storage, control and expiration dates, sharps disposal (SOP), anesthetic monitoring, gas cylinders immobilized, Appropriate hazard signs, carcass disposal, transport of animals to and from animal housing, length of time in procedure room, NYSDOH certificate posted)

Room No.	Α	M	S	SFI	2wks	4wks	Comments
Hall Way		х					The safety shower and eye wash are not being tested weekly or annually (Responsible Party: Facility) **

IACUC Semi-Annual Facility Inspection East Campus: October 28 and Uptown: October 29,2015 -Page 8 of 13

Room No.	Α	M	S	SFI	2wks	4wks	Comments
LSRB B001		x					Wagner Procedure Room: Chemical abbreviations are not permitted. A bottle of ethanol was labeled as 70% ETOH on the cart. All containers must be properly labeled. Some of the containers should be re-labeled with their contents. (Responsible Party: Investigator)*
LSRB B002		х					Wagner Procedure Room: If the cabinet in the laboratory is being used as a bio-safety cabinet, the cabinet must be inspected routinely and the filter must be changed per manufacturer's specification. There were no marking on the cabinet as to when the last inspection was performed. General housekeeping recommendation in the laboratory (Responsible Party: Investigator)*
LSRB B003	х		i				Animal Receiving Room
LSRB B004		х					Chemical abbreviations are not permitted. A bottle of ethanol was labeled as ETOH and a bottle of distilled or deionized water was labeled as dH20 (Responsible Party: Investigator)*
LSRB B005		X		X			Common procedure Area; Wagner & McNay Chemical abbreviations are not permitted. A bottle of ethanol was labeled as 70% ETOH KO 11/25/14 on top of the refrigerator. (Responsible Party: Investigator)* Another similarly labeled bottle was on top of another refrigerator. If hazardous chemicals are no longer being used, they should be disposed of as Hazardous Waste. (Responsible Party: Investigator)* All containers must be properly labeled. The label on the distilled water label on the container was fading and should be relabeled. The label on the Alconox squirt bottle was fading and should be re-labeled. The refrigerator had 4 tubes of frozen material dated 2013/2014. If the material is no longer being used, it should be disposed of accordingly. (Responsible Party: Investigator)* The eye wash is not being tested weekly or annually (Responsible Party: Facility) **

IACUC Semi-Annual Facility Inspection East Campus: October 28 and Uptown: October 29,2015 -Page 9 of 13

Room No.	Α	M	S	SFI	2wks	4wks	Comments
LSRB B005	Х				i		Not in use
LSRB B008		х					(Common Area) Eye wash is not being tested weekly and the last annual inspection was conducted on 11/1/13 (Responsible Party: Facility) **
LSRB BO09		x					(Scimemi Behavioral test room) Chemical abbreviations are not permitted. A bottle of ethanol in a Glass Plus bottle was 'labeled as ETOH (Responsible Party: Investigator)*
LSRB B010	х						(Workman)
LSRB B011	х						Behavioral testing room – Fear Conditioning Box
LSRB B012	Х						Facility storage
LSRB B013	х						(Workman) Water maze pool with PC
LSRB B015		x		х		į	An empty bottle of Coffee-mate was being stored in one of the cabinets. The ceiling had loose joint compound. (Responsible Party: Investigator)*
LSRB B016	х	,					Not in use
LSRB B017	х						Not in use
LSRB B018		x					Not in use The ethanol label on the bottle was fading and should be re-labeled (Responsible Party: Facility) **
LSRB B020	NA						Behavioral test procedure room
LSRB B021	NA						Behavioral test procedure room
LSRB B022	NA		1				Behavioral test procedure room
LSRB B023	NA						Behavioral test procedure room
LSRB B024	NA						Behavioral test procedure room
LSRB B025	NA						Behavioral test procedure room
	1	ose rooms	were in	n use whi	le the ins	pection; t	thus no inspection conducted these 6 rooms
LSRB B026		х					A (4') lamp was sitting on the countertop. Used lamps, ballasts, batteries and certain mercury containing devices are classified as Universal Waste and must be managed accordingly. Improper stored is a violation **User not known
LSRB B027		х					Chemical abbreviations are not permitted. A bottle of ethanol was labeled as 70% ETOH **User not known
LSRB B028		х					Chemical abbreviations are not permitted. A bottle of ethanol was labeled as 70% ETOH **User not known

IACUC Semi-Annual Facility Inspection East Campus: October 28 and Uptown: October 29,2015 -Page 10 of 13

Room No.	Α	M	S	SFI	2wks	4wks	Comments
LSRB B029		х					Chemical abbreviations are not permitted. Two bottles of ethanol was labeled as 70% ETOH. **User not known
LSRB B030		X		x			The light switch was obstructed by the Suncast cabinet. Suggest moving the cabinet to a new location. Chemical abbreviations are not permitted and all containers must be properly labeled. A bottle of ethanol was labeled as 70% ETOH and the label was fading. Another bottle was labeled 70% ETOH KO 11/25/14 on top of the cart. If hazardous chemicals are no longer being used, they should be disposed of as Hazardous Waste. **User not known
LSRB B031		x		х			The light switch was obstructed by equipment. Suggest moving the equipment to a new location. The eye wash is not be tested weekly or annually. (Responsible Party: Facility) **
LSRB B033	х						Break Room for Animal care staff
LSRB B034							(Storage) A surge protector was plugged into another surge protector and the cord was running into B-033 via a hole in the wall. This is a fire safety violation (Responsible Party: Facility) **
LSRB B035							Larsen and Forni Common Area: Chemical abbreviations are not permitted. Three bottles of ethanol were labeled as 70% ETOH. Two additional bottles were labeled as PBS (Responsible Party: Investigator)*
LSRB B038		х		х			The eye wash is not being inspected weekly or annually. Review of the drug inventory log suggests updating the labeling system to identify those drugs being stored outside of B-038. (Responsible Party: Facility) **
Bio 338 A	х						Scimemi Lab

Animal Housing and Support Areas - Aquatic Specific

(standards for acceptable quality are established, chlorine, chloramines, chemical, and reactive bioproducts are removed or neutralized prior to use in aquatic systems, primary enclosure provides a balanced, stable environment Construction allows undisturbed observation and with nontoxic materials, prevents electrical hazards, environment enrichment elicits appropriate behaviors and is safe semi-aquatic reptiles are provided terrestrial areas, nets are cleaned, disinfected and managed to avoid contamination of systems, water quality parameters and frequency of testing recorded, records kept on feeding, non-expired food supplies, live cultures, frequency of tank/cage cleaning and disinfection is determined by water quality, permits adequate viewing and health monitoring

Room No.	Α	M	S	SFI	2wks	4wks	Comments
Bio 25	х		Х				There are holes on the wall for piping. Holes need to be fixed (Responsible Party: Facility) **
Bio 24	Х		Х				

REPORT SUMMARY

Note: Please check the box above ONLY if no data has been entered on the inspection form.

Deficiencies

- > For each deficiency identified, specify the "correct by date."
- ➤ LAR is responsible for addressing all deficiencies (significant and minor) within the timeframe required by the IACUC, and informing the IACUC (via ORRC) of the final resolution.
- > When Suggestions for Improvement are made, LAR must address whether or not the suggestions were incorporated.
- > Significant deficiencies that are not corrected within the required timeframe must be reported to the appropriate regulatory agency.

Room No.	Acceptable	Minor deficiencies	Significant deficiencies	Suggestions For Improvements

Signature: All subcommittee members conducting this inspection must sign below.					
Print Donald Orokos	Signature				
Print Nay Gosai	Signature				

IACUC Semi-Annual Facility Inspection East Campus: October 28 and Uptown: October 29,2015 -Page 12 of 13

REPORT SUMMARY

☐ We have inspected all the listed rooms and found no deficiencies.					
ote: Please check the box above ONLY if no data has been entered on the inspection form.					
		Deficien	cies	1	
➢ For e	each deficiency id	entified, specify the "c	orrect by date."		
	rame required by	addressing all deficie the IACUC, and inforr		d minor) within the a ORRC) of the final	
	n Suggestions for estions were inco	· Improvement are marporated.	de, LAR must addre	ess whether or not the	
_		s that are not correcter riate regulatory agenc		timeframe must be	
Room No.	Acceptable	Minor deficiencies	Significant deficiencies	Suggestions For Improvements	
Commenda	ations:				
otes/com	men t s:				
	444				
Signatu	re: All subcomn	nittee members cond	ucting this inspecti	on must sign below.	
rint Donald	Orokos	Sig	gnature -	W/	
rint Nay Gos	sai	Sig	mature	}	

Notes/comments: Administrative Notes

For both East Campus and Uptown Campus;

- (1) Many signees outdated (there are signage that include previous facility manager's name) on facility doors
- (2) Many signage on animal housing area outdated name of investigator, protocol number(s) and lab contact person information.
- (3) There is no contact information or post for "report for concern" to the ORRC.

Uptown Campus;

- (1) Note for LSRB 049 -Scimemi Procedure Room; this procedure room is locate in the animal housing area. Is this acceptable?
- (2) Drug Safe during this inspection, the IACUC notified there are 3 drugs keep in out of animal facility/drug safe area.
 - ** LSRB 1042 (Wagner lab): Testosterone stored in safe (There is no note and record on protocol file and IACUC meeting minutes)
 - ** LSRB 1067 (cold room/Gervasi Lab): Because the drug must keep it in freezer and Animal facility don't have freezer (There is no note and record on protocol file and IACUC meeting minutes)
 - ** Biology (Zuloaga Lab): Cocaine stored in the biology building Solution for the drug cannot bring in the animal facility thus investigator make drug at his lab and bring into animal testing lab (There is no note and record on protocol file and IACUC meeting minutes)
- (3) IACUC requested to the ORRC to contact the building manager of Biology building to fix holes on wall (Bio 24 and 25); this need to be notified PI and fixed by the Facility (not the compliance office)

(1)Listed items below reported deficiency on 10/29/2015 Main Campus Facility Inspection.

Room No.	Findings	* Listed items corrected	** Listed items corrected	Comments
Animal Housing Rooms	Signs on all animal housing rooms needs to be update such as Protocol numbers, Lab contact person information, Personnel		NO	Facility received updated posting for each animal room containing current protocol numbers and contact details.
Hall Way	All The safety shower and eye wash are not being tested weekly or annually	X On Process		On process to set up weekly or annual test – LAR sent a note the Life Science building manager
Procedures Rooms	All The safety shower and eye wash are not being tested weekly or annually	X On Process		regarding the eyewash and safety shower testing issue. The LAR are working out how best to
Common/S hare area	All The safety shower and eye wash are not being tested weekly or annually	X On Process		accomplish this task i.e., with LAR or facility staff.
LSRB B039A Surgery Room	The floor drain for the auto-clave is corroding and should be cleaned/replaced. All containers must be properly labeled. Two containers (possibly empty) under the sink were missing labels.	ed. All containers must be developed developed		printed labels have been
Room locate at animal housing area Flammables are not permitted to be stored in a regular refrigerator due to an explosion hazard. Chemical abbreviations are not permitted. Two tubes were labeled as ETOH and being improperly stored in a regular refrigerator. This is a fire safety			х	Action needed on this item (3/25/16)
violation. Necropsy Room: Hazardous waste should be disposed of on a regular basis. The cabinets under the hood contained an excessive amount of		Х		PI to be notified to arrange for the removal of waste.
hazardous waste. Necropsy Room: The Spill-X-FP for formaldehyde spills is no longer usable and should be replaced with a new one. All containers must be properly labeled. Two carboys were labeled with the PI's (McNay) name.		X On Process		A new kit will be order the week of 3/27.
Cage wash, clean side: All containers must be properly labeled. The white (possibly empty) carboy next to the Quadracide container was missing a label. It was mentioned that the cleaning system is not functional or is not being used. If so, containers from this system should be disposed of accordingly.		X		Labeling of chemicals: Pre- printed labels have been developed

IACUC Semi-Annual Facility Inspection FOLLOW UP items $\,$ -Page ${\bf 1}$ of ${\bf 4}$

Room No.	Findings	*Listed items corrected	* Listed items corrected	Comments
LSRB B043	Cage wash, dirty side: Eye wash is not being tested weekly and the last annual inspection was conducted on 11/1/13.	X On Process		On process to set up weekly or annual test — LAR sent a note the Life Science building manager regarding the eyewash and safety shower testing issue. The LAR are working out how best to accomplish this task i.e., with LAR or facility staff.
LSRB B018	The ethanol label on the bottle was fading and should be re-labeled	Х		Labeling of chemicals: Pre- printed labels have been developed
LSRB BO26	A (4') lamp was sitting on the countertop. Used lamps, ballasts, batteries and certain mercury containing devices are classified as Universal Waste and must be managed accordingly. Improper stored is a violation			Lamp to be disposed of week of 3/27
LSRB B027	Chemical abbreviations are not permitted. A bottle			Labeling of chemicals: Pre- printed labels have been developed
LSRB B 028	Chemical abbreviations are not permitted. A bottle of ethanol was labeled as 70% ETOH			Labeling of chemicals: Pre- printed labels have been developed
LSRB B 029	Chemical abbreviations are not permitted. A bottle of ethanol was labeled as 70% ETOH			Labeling of chemicals: Pre- printed labels have been developed
LSRB B 030	The light switch was obstructed by the Suncast cabinet. Suggest moving the cabinet to a new location. Chemical abbreviations are not permitted and all containers must be properly labeled. A bottle of ethanol was labeled as 70% ETOH and the label was fading. Another bottle was labeled 70% ETOH KO 11/25/14 on top of the cart. If hazardous chemicals are no longer being used, they should be disposed of as Hazardous Waste.			Room arrangement will be discussed with the PI. Labeling being addressed as indicated earlier.
LSRB B 031	The light switch was obstructed by equipment. Suggest moving the equipment to a new location. The eye wash is not be tested weekly or annually.	X On Process		Same as above.
LSRB B 032	A surge protector was plugged into another surge			A new, longer cord will be ordered.
LSRB B 038	Review of the drug inventory log suggests updating			
Bio 025	There are holes on the wall for piping. Holes need to be fixed	X		Facility management contacted to initiate repairs in the areas identified in the inspection report.

Room No.	Findings	Listed items corrected	Listed items corrected	Comments
		YES	NO	
LSRB 060 Paulos Lab	Poulos Lab - Rats Protocol # error on cage card	X		Cage cards were corrected at the time of the inspection. PI and research staff notified of the mislabeling.
LSRB 049 Scimemi Lab	Chemical abbreviations are not permitted. Two bottles of ethanol were labeled as 70% ETOH on the countertop. A bottle was labeled as dH20. A bottle was labeled as PBS.	Х		Labeling of chemicals: Pre- printed labels have been developed
LSRB B001 Wagner Procedure Room	Chemical abbreviations are not permitted. A bottle of ethanol was labeled as 70% ETOH on the cart. All containers must be properly labeled. Some of the containers should be re-labeled with their contents.	Х		Labeling of chemicals: Pre- printed labels have been developed
LSRB B001 Wagner Procedure Room	If the cabinet in the laboratory is being used as a bio-safety cabinet, the cabinet must be inspected routinely and the filter must be changed per manufacturer's specification. There were no marking on the cabinet as to when the last inspection was performed. General housekeeping recommendation in the laboratory	X		Room was cleaned. The cabinet utility is being discussed with the PI.
LSRB B004 Wagner Procedure Room	Chemical abbreviations are not permitted. A bottle of ethanol was labeled as ETOH and a bottle of distilled or deionized water was labeled as dH20	Х		Labeling of chemicals: Pre- printed labels have been developed
LSRB B005 Common procedure Area; Wagner McNay	Chemical abbreviations are not permitted. A bottle of ethanol was labeled as 70% ETOH KO 11/25/14 on top of the refrigerator.	Х		Labeling of chemicals: Pre- printed labels have been developed
LSRB B005 Common procedure Area; Wagner &McNay	Another similarly labeled bottle was on top of another refrigerator. If hazardous chemicals are no longer being used, they should be disposed of as Hazardous Waste	х		Same as above.
LSRB B005 Common procedure Area; Wagner & McNay	All containers must be properly labeled. The label on the distilled water label on the container was fading and should be re-labeled. The label on the Alconox squirt bottle was fading and should be relabeled. The refrigerator had 4 tubes of frozen material dated 2013/2014. If the material is no longer being used, it should be disposed of accordingly	х		Same as above.

Room No.	Findings	Listed Items corrected YES	Listed items corrected	Comments
LSRB 009 Scimemi Lab	Scimemi Behavioral test room Chemical abbreviations are not permitted. A bottle of ethanol in a Glass Plus bottle was labeled as ETOH	X		Labeling of chemicals: Pre- printed labels have been developed
LSRB B015	An empty bottle of Coffee-mate was being stored in one of the cabinets. The ceiling had loose joint compound.	X		Facility repair being discussed and planned. Container will be disposed of.
LSRB B035 Common Area: Larsen & Forni	Chemical abbreviations are not permitted. Three bottles of ethanol were labeled as 70% ETOH. Two additional bottles were labeled as PBS	Х		Labeling of chemicals: Pre- printed labels have been developed

UNIVERSITY AT ALBANY INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

IACUC Semiannual Program Evaluation Thursday, November 19, 2015 9:30 am LSRB 1144

IACUC Members:

Name	Role	Present Y/N
B. Parr	Chair	Y
M. Bergkvist	Scientist	Y
W. Carpenter	Non-Affiliated, Non-Scientist	N
N. Gosai	Non-Scientist	N
A. McKenna	Attending Veterinarian	Υ
D. Orokos	Scientist	Y

Other Attendees:

Adrienne Bonilla:

Asst. VP for Research, UA Compliance Officer

Timothy Quinn: Jeffrey Horowitz: Laboratory Animal Facilities Manager Regulatory Compliance Administrator

Megan Mosher: Kanako Sumida-Ervin: Regulatory Compliance Administrator Regulatory Compliance Administrator

Terrell Rabb:

Regulatory Affairs Administrator

AGENDA

- 1. Greetings and Introductions All
- 2. Welcome -Asst. VP for Research, A. Bonilla
- 3. Semiannual Program Review IACUC Chair Parr, IACUC
 - A- Review of last program review (May 20, 2015)
 - **B- Semiannual Program Review**

Checklist review – Attendees will break into two groups with each group completing one half of the Semiannual review checklist.,

After completion of checklist review, the two groups will reunite; discuss the findings, and document the Semi-Annual Report Summary.

4. Meeting adjourned - 10:30 AM

Findings IACUC Semi-Annual Program Review May 20, 2015

There are no deficiency or concerns reported May 20, 2015 – 2 items listed as suggestion for improvement item.

Deficiency or Suggestion for Improvement	IACUC training
Description	The IACUC member training is still in progress; "Training on how to inspect facilities and labs where animal use or housing occurs (Guide, p 17)."
	C: Suggestion For Improvement
Date Correction or Suggestion Completed	October 2015 Inspections - The Chair distributed a short list of inspection checklist for IACUC facility inspection. The ORRC prepared the list of active protocols and list of animal number/species, and expiration date
Person & Office Responsible for Correction	ORRC/IACUC

Deficiency or Suggestion for Improvement	Other
Description	Members also suggested to seek the information of University policy for personnel security (item 11. Preventive measures in place include pre-employment screening, and physical and IT security (Guide, p 23)) to enhance safety for animal use programs and facilities.
	C: Suggestion For Improvement
Date Correction or Suggestion Completed	By next semi-annual Review
Person & Office Responsible for Correction	PI/LAR

5. Euthanasia	Α*	М	S	C I	NA
 Methods are consistent with AVMA Guidelines on Euthanasia unless approved by the IACUC (Guide, p 123) 	X				
Standardized methods are developed and approved by the veterinarian and IACUC that avoid distress and consider animal age and species (Guide, pp 123-124)	X				
 Training is provided on appropriate methods for each species and considers psychological stress to personnel (Guide, p 124) 	X				
Procedures and training are in place to ensure death is confirmed (<i>Guide</i> , <u>p 124</u>) must	X				
6. Drug Storage and Control	Α*	М	S	C I	NA
 Drug Storage and Control Program complies with federal regulations for human and veterinary drugs(Guide, p. 115) must. 	X	М	S	C I	NA
 Program complies with federal regulations for human and veterinary drugs(Guide, p 115) Drug records and storage procedures are reviewed during facility inspections (Guide, p 115) 	X	М	S	C 1	NA
 Program complies with federal regulations for human and veterinary drugs(Guide, p 115) must Drug records and storage procedures are reviewed during facility inspections (Guide, p 	X	M	S	C	NA

IACUCSEMI-ANNUAL REPORT SUMMARY

FINDINGS

- > For each finding or deficiency identified above, provide description, whether Minor or Significant (if deficiency), correct-by date, name of individual and his/her office responsible for making the correction.
- > The IACUC (ORRC) will follow up with responsible person for status report by correction due date. Justification will be required if deficiency(ies) are not corrected by the due date.
- > Significant deficiencies that are not corrected within the required timeframe must be reported to the appropriate regulatory agency.

Deficiency or Suggestion for Improvement	Description	If Deficiency - Minor or Significant	Correct by Date	Person & Office Responsible for Correction	Date Correction or Suggestion Completed
Suggestion for Improvement	Plans describe preservation of critical or irreplaceable animals (<i>Guide</i> , <u>p 35</u>) - Evacuation procedure may recommend to investigators for irreplaceable animal if applicable.	NA	Next Semi- Annual Meeting	Antigone McKenna (Inform to all animal user by e-mail)	

 \boxtimes

We have completed the program review and found no deficiencies.

**Signatures on last page **

II. Endnotes

- ⁱ The PHS Policy requires that Assured institutions comply with the regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act, as applicable. The endnotes below are specific USDA regulatory requirements that differ from or are in addition to the PHS Policy. This list is not intended to be all inclusive. For additional information please refer to 9 CFR Subchapter A Animal Welfare.
- ii Part 2 Subpart C Research Facilities
- 2.31(b)(2) "The Committee shall be composed of a Chairman and at least two additional members;... at least one shall not be affiliated in any way with the facility...such person will provide representation for general community interests in the proper care and treatment of animals." [PHS policy requires 5 members]
- 2.32(c)(4) "...No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act." [USDA requirement additional to PHS Policy]
- iv 2.31(d)(5) "...shall conduct continuing reviews of activities...not less than annually." [PHS Policy requires a complete new review every 3 years utilizing all the criteria for initial review]
- v 2.31(d)(1)(x) "...no animal will be used in more than one major operative procedure from which it is allowed to recover unless...(it is) justified for scientific reasons...(or is) required as routine veterinary procedure...or other special circumstances as determined by the Administrator on an individual basis." [this last point is an additional USDA justification for multiple survival surgeries]
- vi 2.36(b)(3) "...exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report." [Refers to USDA annual report]
- vii 2.31(c)(3) "...Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the institutional official, to APHIS and any Federal agency funding that activity." [PHS Policy requires prompt reporting to OPRR of serious or continuing noncompliance with the PHS Policy or serious deviations from the provisions of the Guide]
- viii 2.36 "...each reporting facility shall submit an annual report to the APHIS, AC sector supervisor for the State where the facility is located on or before December 1 of each calendar year." [The USDA annual report has a list of requirements which differ from PHS annual report]
- ix In addition to PHS requirements for IACUC review/application for funding, USDA regulations require:
 - 2.31(d)(1)(ii) "The principal investigator (PI) consider alternatives to procedures that cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources...used to determine that alternatives were not available."
 - 2.31(d)(1)(iii) "The PI has provided written assurance that the activities do not unnecessarily duplicate previous experiments."
 - 2.31(d)(1)(iv) "Procedures that may cause more than momentary or slight pain or distress to the animals will:
 - involve in their planning, consultation with the attending veterinarian or his or her designee; [PHS Policy does not specify veterinary consultation]
 - not include paralytics without the use of anesthesia;"
 - 2.31(d)(1)(x) "No animal will be used in more than one major operative procedure from which it is allowed to recover, unless justified for scientific reasons by the principal investigator, in writing..."
- × 2.33(a)(1) "In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility." [USDA requirement additional]
- xi 2.32(c) "Humane methods of animal maintenance and experimentation, including the basic needs of each species, proper handling and care for the various species of animals used by the facility, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures."
- xii 2.32(c) additional specifications include:
- "proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility"
- "methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility..."
- "utilization of services (e.g., National Agricultural Library, National Library of Medicine) to provide information on appropriate animal care and use, alternatives to the use of live animals in research, that could prevent unintended and unnecessary duplication of research involving animals, and regarding the intent and requirements of the Act." [USDA training specifications are more detailed than PHS Policy].
- xiii 2.31(d)(iv)(C) "Procedures that may cause more than momentary or slight pain or distress to the animals will...not include the use of paralytics without anesthesia."

JACUCSEMI-ANNUAL REPORT

November 19, 2015

	We ha							

Note: Please check the box above ONLY if all items were found to be "Acceptable" on the checklist.

Signature: All members conduct	ling this program review must sign below.
Brian Parr	Brian Pan
Nay Gosai	
Antigone McKenna	ADD
Donald Orokos	HAN Head
William Carpenter	
Magnus Bergkvist	44



TO:	Institutional Animal Care and Use Committee
FROM	Adrienne D. Bonilla, Asst. VP for Research
RE:	IACUC Semi-Annual Report Reporting Period: Sept 1, 2015 – Feb 29, 2016
	ed is the IACUC Semi-Annual Report to the Vice President for Research on the sity's Animal Care and Use Program. Please review, and sign at the bottom.
•	10/28/15 IACUC Inspection of East Campus Laboratory Animal Facility 10/29/15 IACUC Inspection of Main Campus Laboratory Animal Facility 11/19/15 IACUC Semi-Annual Review UAlbany Animal Care and Use Program
l have	read the report and I, Magnus Bergkvist (Printed Name)
	(i timed warne)
	Approve:
,	(Member Signature)
	b
	Disapprove: (Comments below)
	(Member Signature)
	COMMENTS:



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I have read t	he report and I, Nay Gosti (Printed Name)
Appro	ove:
	(Member Signature)
Disap	pprove: (Comments below)
	(Member Signature)
COM	MENTS:

MSC 309



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have	read the report and I,, (Printed Name)
	Approve:
	(Member Signature)
	49
	Disapprove: (Comments below)
	(Member Signature)
	COMMENTS:



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I have read	the report and 1, Antigone McKenne, (Printed Name)
Аррі	(Member Signature)
Disa	pprove: (Comments below)
	(Member Signature)
CON	MMENTS:

MSC 309 1400 Washington Ave, Albany, NY 12222 PH: 518-437-3850 FX: 518-437-3855 www.albany.edu/orrc



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I have r	read the report and I,, (Printed Name)
,	Approve:
	Brian Pan
	(Member Signature)
	74
	Disapprove: (Comments below)
	(Member Signature)
	COMMENTS:
	Thank you!

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	(Member Signature)
	(Melyhber orginataro)
	Disapprove: (Comments below)
	(Member Signature)
	COMMENTS: