Tulane University A4499-01

Animal Welfare Assurance for Domestic Institutions

I, **Laura Levy, PhD** as named Institutional Official for animal care and use at **Tulane University**, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

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

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

"Institution" includes the following branches and major components of Tulane University:

- **Tulane National Primate Research Center (TNPRC or "the Center")**
- **New Orleans Campuses - includes both the Downtown and Uptown campuses**

B. The following are other institution(s), or branches and components of another institution:

Southeast Louisiana Veterans Health Care System

II. Institutional Commitment

A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

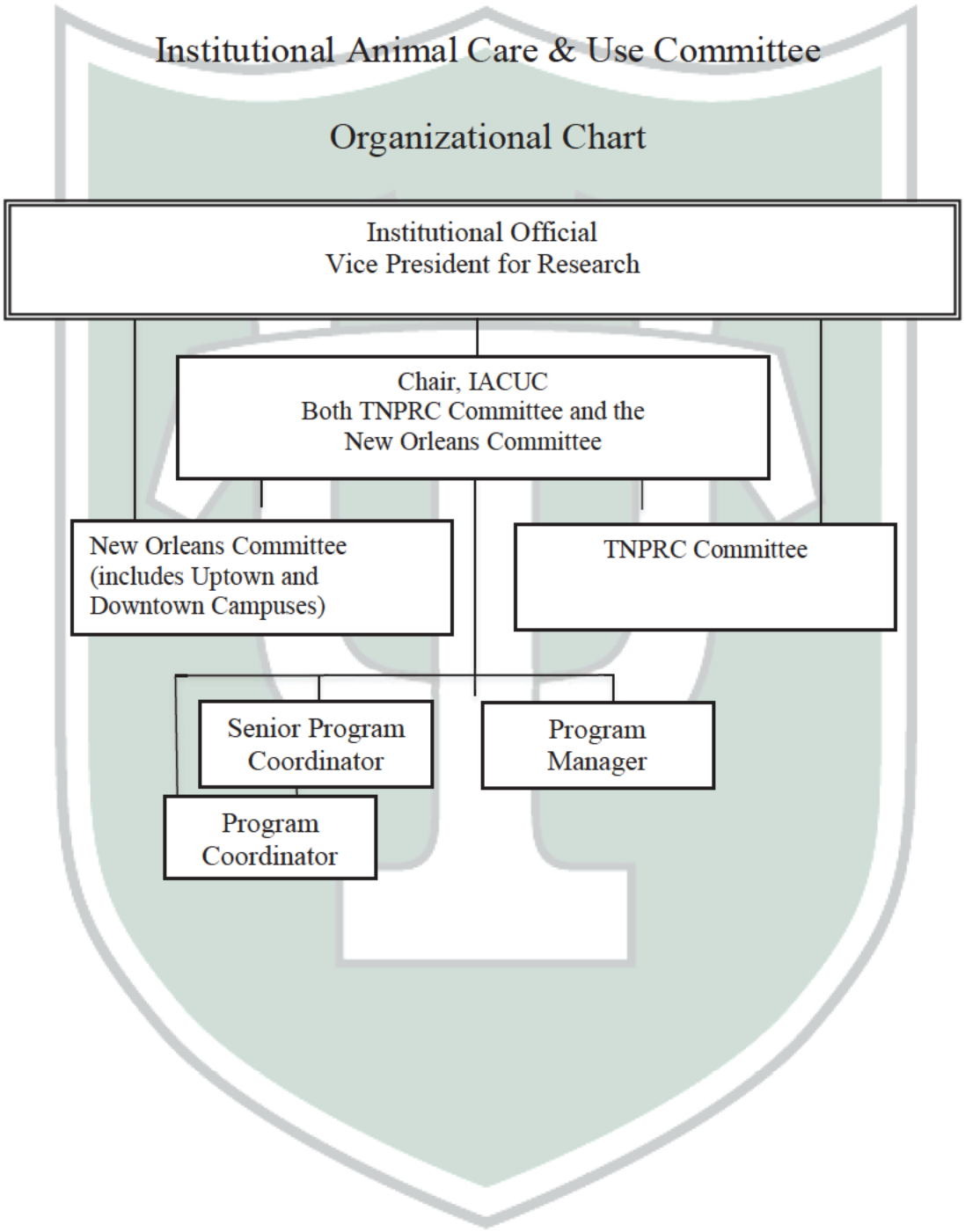
C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand 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*).

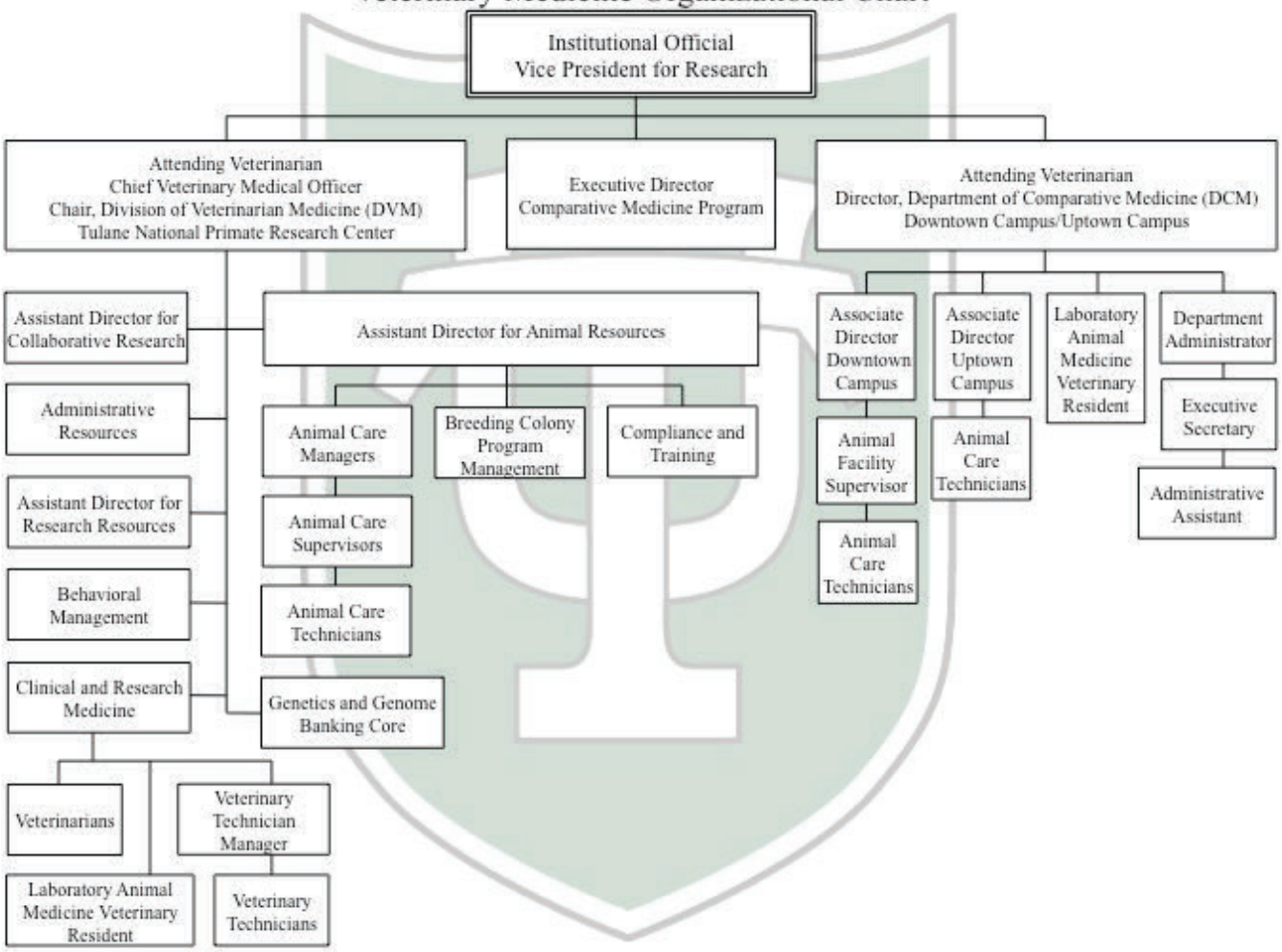
E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use

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



Veterinary Medicine Organizational Chart



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

TNPRC

All veterinarians at the TNPRC are employed full-time by Tulane University. The percentage of time dedicated to the animal care and use program for each veterinarian is listed below. Minimum qualifications for veterinarians that provide unsupervised veterinary care for the program are: graduation from a veterinary school accredited by the AVMA Council on Education, certification by the Educational Commission for Foreign Veterinary Graduates (ECFVG) or North American Veterinary Licensing Examination (NAVLE), and veterinary licensure in at least one state in the US. Clinical veterinarians are responsible for administering the preventive medicine program and provision of medical care to breeding colony animals. Veterinarians also provide research support services and health care to animals assigned to research protocols. Veterinary residents (post-doctoral fellows) in the Tulane University Laboratory Animal Medicine Training Program assist clinical veterinarians in the performance of their duties as part of their training program. Veterinary pathologists interpret clinical pathology diagnostics, interpret histopathology, and perform necropsies and post-mortem diagnoses on colony and research animals as part of the preventive health program.

Clinical Veterinarians:	% Support Provided
James Blanchard, DVM, PhD, DACLAM	50%
Rudolf Bohm, Jr., DVM, DACLAM	100%
(b) (6)	100%
	100%
	100%
	100%
	100%
	100%
	100%
Laboratory Animal Medicine Residents:	
(b) (6)	20%
	80%
Veterinary Pathologists:	
(b) (6)	100%
	100%
	100%
	50%

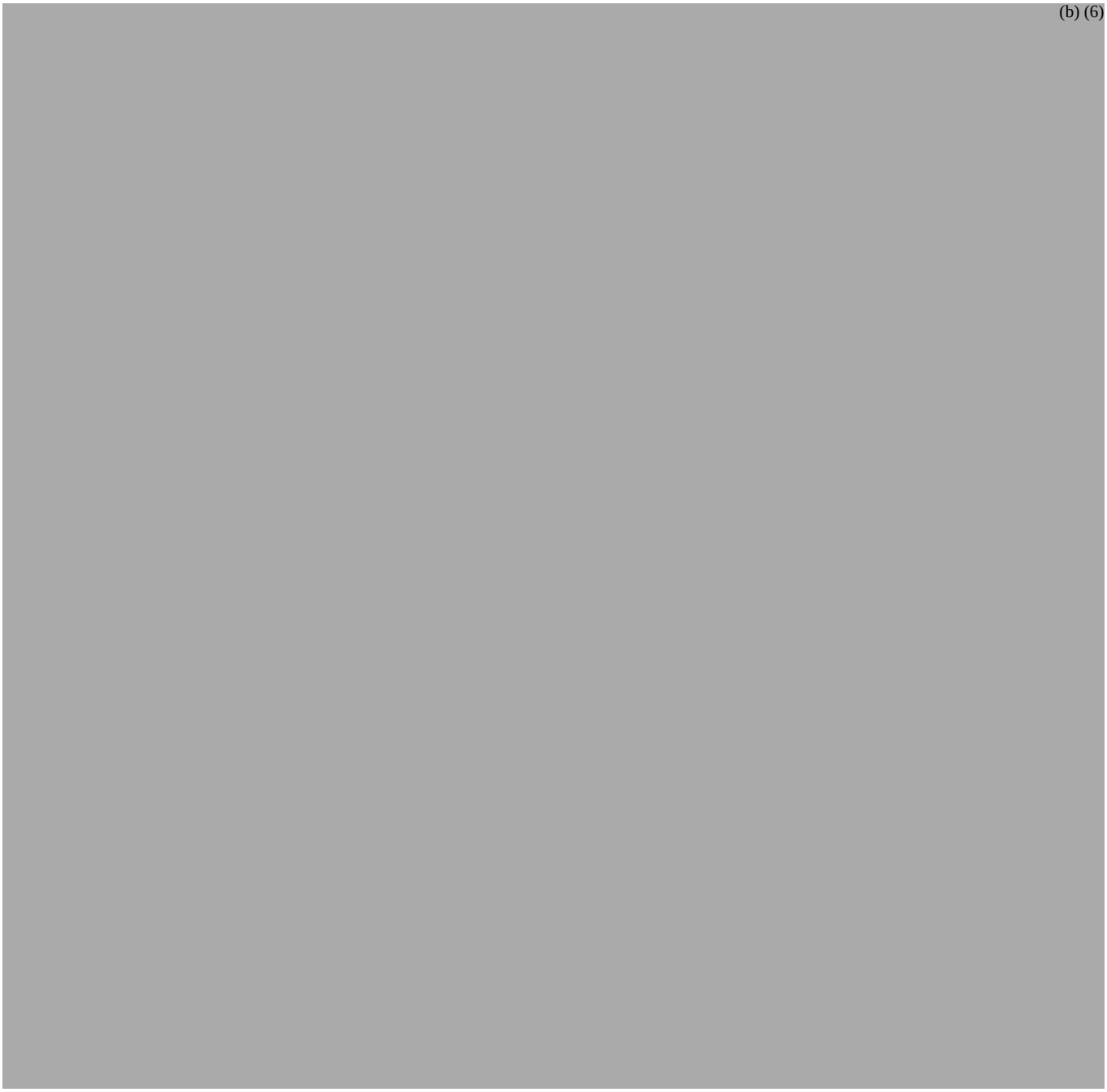
Veterinarians

Rudolf P. Bohm Jr., DVM, DACLAM Associate Director and Chief Veterinary Medical Officer (CVMO), Chair, Division of Veterinary Medicine, TNPRC, and Professor of Medicine, Department of Medicine, Tulane School of Medicine. He is the Director of the Tulane University Laboratory Animal Medicine Training Program. Dr. Bohm has direct Program Authority and responsibility for the Institution's animal care and use program at the TNPRC including access to all animals. Dr. Bohm has 28 years of experience in the practice of laboratory animal medicine with a focus on nonhuman primate medicine and surgery. Dr. Bohm is a past president of the Association of Primate Veterinarians (APV), and currently an *ad hoc* Primate Specialist for the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) International. He is the Chair of the NIH Nonhuman Primate Breeding Colony Management Consortium. He is a member of NPRC external scientific advisory committees. At the TNPRC he also serves as Chair of the Tulane Resource Allocation Committee (TRAC) and as a member of the IACUC and Executive Committee. Dr. Bohm is also a member of the Editorial Board of the Journal of Medical Primatology. As the Associate Director and CVMO, Dr. Bohm is a member of the TNPRC senior leadership team, which includes the Chief Operations Officer and the Director. He shares responsibilities with the Chief Operations Officer in advising the Director in financial affairs, administration, development, growth management, strategic planning and

master planning. Dr. Bohm provides leadership to the animal resources program as Chair of the Division of Veterinary Medicine along with the Assistant Directors of Animal Resources, Collaborative Research, and Research Resources.

James L. Blanchard, DVM, PhD, DACLAM Interim Director, TNPRC, Professor, Department of Medicine, Tulane School of Medicine, Executive Director, Comparative Medicine Program. He has advanced training in pathology and parasitology and 33 years experience in nonhuman primate medicine and surgery. Dr. Blanchard is currently the Head of the Unit of Clinical and Research Medicine and works closely with the Chair of Veterinary Medicine to facilitate the mission of the Division of Veterinary Medicine. Dr. Blanchard also serves as Assistant Director of the Laboratory Animal Medicine Training Program. Dr. Blanchard is past president of the Association of Primate Veterinarians, past president of the Louisiana Branch AALAS, and served as a member of the NIH Comparative Medicine Review Committee from 2005-2010. He is a consultant to the Tulane Institutional Animal Care and Use Committee, and oversees the University Comparative Medicine Program. Dr. Blanchard is member of the Editorial Board of the Journal of Medical Primatology. As Interim Director of the TNPRC Dr. Blanchard works closely with the Chief Operations Officer and Chief Veterinary Medical Officer to provide oversight of daily functions of the Center and continued advancement of the research program.

(b) (6)



Laboratory Animal Medicine Residents

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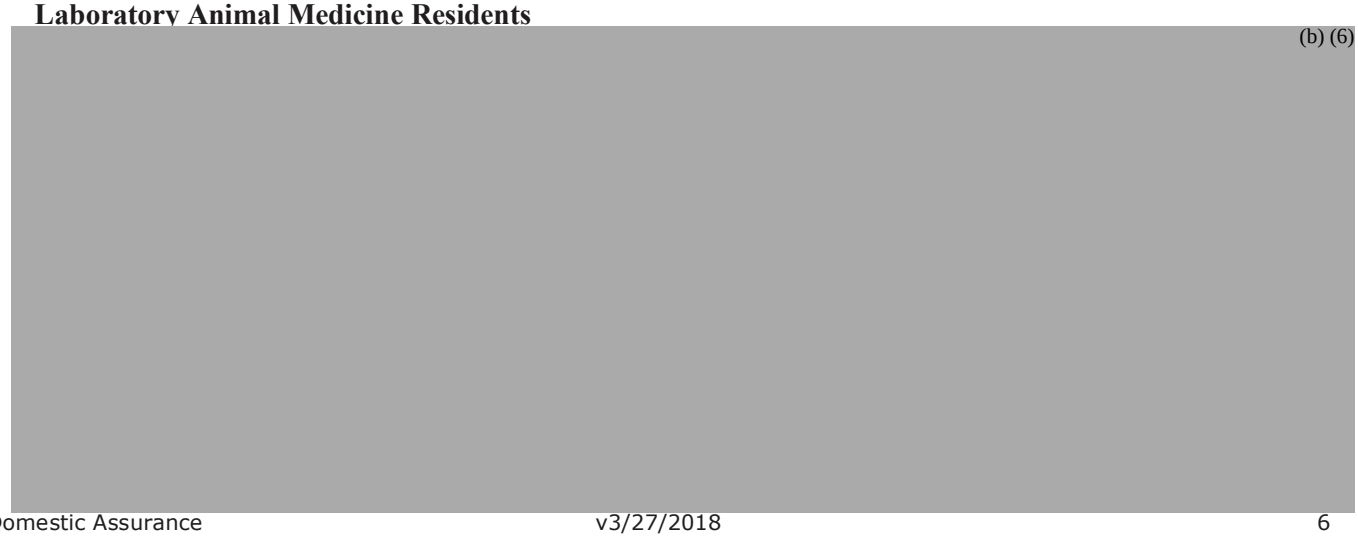

(b) (6)

[redacted]

Department of Comparative Medicine (Downtown and Uptown Campuses)
The Department of Comparative Medicine (DCM) has one full time veterinarian responsible for the care of all animals at the Downtown Campus (DT) and the Uptown Campus (UT). The veterinarian devotes 100% of her time to the department. Back-up veterinary care is provided by two laboratory animal medicine residents, Monica Shroyer, DVM and David Andrews, DVM.

Name of Veterinarian(s)	**If full time, indicate time dedicated to animal care and use program**
Georgina L. Dobek, DVM, DACLAM Direct Program Authority and responsibility for the Institution's animal care and use program including access to all animals on the New Orleans Campuses.	100% Full time employee
(b) (6) [redacted]	80%
	20%

Georgina L. Dobek, DVM, DACLAM Director, Department of Comparative Medicine (DCM) and Assistant Professor of Clinical Medicine, Tulane School of Medicine. Dr. Dobek has direct program authority and responsibility. Dr. Dobek was appointed the Director in June 2013. Dr. Dobek received her DVM from Texas A&M University and completed a residency in Laboratory Animal Medicine at Tulane University. She has been a Diplomate of ACLAM since 2012 and has 8 years of experience in the field. She is an Assistant Professor of Clinical Medicine in the School of Medicine. She is also the Attending Veterinarian member of the New Orleans (Downtown /Uptown Campus) IACUC and a member of Tulane's Institutional Biosafety Committee. In addition, Dr. Dobek is active in several national organizations, including the Association of Laboratory Animal Practitioners and American College of Laboratory Animal Medicine.

(b) (6)

C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b.

Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

A PI cannot choose a committee for the assignment of his or her proposed activities. Assignment to a committee is based on the location of the faculty appointment of the PI submitting the work unless the PI has a faculty appointment at the Uptown or Downtown campus and will be using nonhuman primates (NHPs). If the PI is using NHPs the TNPRC campus IACUC reviews the protocol.

Consistency and communication across the committees is achieved through the following:

- The Tulane IACUC Advisory Committee (TIAC) was created to develop program wide policies, establish greater consistency, and enhance communication across the program. The TIAC is made up of six members, two members from the TNPRC IACUC (AV and one PI), two members from the NOC IACUC (AV and one PI), the Research Compliance Officer, IACUC Chair and a Chair appointed by the IO. The chair of this committee is a member of one of the IACUC. The IO is responsible for appointments to this committee and the term of service is two years. This committee meets at least three times per year and is responsible for discussion and review of practices and policies to ensure program consistency between committees. All recommendations and proposals from this committee would be presented to the full committee for review and approval.
- One chair for both committees.
- All IACUC SOPs and policies undergo review and approval on a triennial basis by both committees.
- A central IACUC office administers documentation and record keeping.
- Training materials and presentations are presented to both IACUC committees for review.
- The Biosafety Specialist is a voting member on both committees and provides expertise relating to all biohazards. She is also a liaison to the Institutional Biosafety Committee.
- The Environmental Health Safety Specialist at the TNPRC is an *ad hoc* member who is provided access to meeting materials. She is required to provide expertise regarding chemical or physical hazards and that information is provided to the Division of Veterinary Medicine. She works with and consults with the OEHS member that sits on the New Orleans campus IACUC.

D. The IACUC will:

1) Review at least once every 6 months the Institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

Program Review: The following programs at the Tulane University are subject to review every six months by the IACUC.

- IACUC (includes training)
- Veterinary Medicine (incudes training)
- Occupational Health & Safety (includes training)
- Behavioral Management (TNPRC)

The AAALAC program description is used as a guide for the program review. The OLAW checklist is required as an adjunct to the program description and is used as a guide to identify areas of the program that need improvement or revision. Program Reviews are submitted by the Director/Coordinator for each program. These reports include an overview of their program highlighting any changes within the last six months including goals accomplished, changes in membership or staffing, completed tasks and should also note future goals for the program. The report also identifies any minor or significant deficiencies and a correction plan and timetable for correction. These reports are presented to the committee for review at the Semiannual Inspection and Program Review Meeting. These meetings are held twice a year and may be separate from the regularly scheduled IACUC meeting. All IACUC members are invited to participate in the semiannual program review. The Director/Coordinator for each program or their designee presents their respective Program Review to the committee. The IACUC reviews each program description and, if necessary, the IACUC may vote to determine if certain deficiencies are categorized as minor or significant. Members document their approval of the Semiannual Review of Animal Care and Use Programs by providing their signatures. Any member wishing to file a minority report may do so and it will be presented to the IO and included in the annual OLAW report. The members who are not present at the meeting are given an opportunity to submit a written minority report.

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:

Inspection of Facilities

a. TNPRC - All animal facilities and satellite animal facilities currently used for housing, holding, breeding, experimenting, transporting, or sanitizing; or have been used for such within the past six months or are projected to have such use within the next six months are inspected.
b. New Orleans Campus - All individual labs that conduct any procedure involving live animals; are inspected every 6 months. The Department of Comparative Medicine (DT and UT) animal facilities are inspected every 6 months.
c. Inspections take place semiannually.
d. Inspections may or may not be scheduled in advance with the area supervisor and/or PI.

Inspection Teams and Assignments

a. The IACUC Program Manager (PM) assigns teams of two or three committee members to specific inspection areas. The PM is charged with noting all comments and a summary report. All summary reports are sent to team members for review. Teams stay together and inspect the same location for approximately two years in order to achieve consistency of review and a better quality inspection. New members to each team rotate in during the end of the second year thereby ensuring one member of the team from the previous inspection. Any IACUC member is welcome to participate in any inspection and this is communicated before every inspection.

b. *Ad hoc* consultants may assist in the inspections, as requested by the IACUC.

Inspection Packets - Each team has available for review:

a. Previous inspection summary from that area. This summary lists the overall condition and any deficiencies. Teams should take note of any deficiencies that are still present from the last inspection and note these on the checklist.
b. Inspection checklist specific for each area. This checklist includes the types of procedures conducted, species, and approved euthanasia methods.
c. A list of items to be looking for during the inspection, which is taken from the Guide.
d. Information list of significant vs. minor deficiencies.
e. Instructions for how to conduct an inspection.
f. Each team member is encouraged to refer to PHS Policy, the Guide, and USDA regulations for specific facility issues that might arise during the conduct of the inspection.

Inspection Process

a. For each inspection area, IACUC members use the provided checklists to rate items as acceptable (A), minor deficiency (M), significant deficiency (S), or non-applicable (NA).
    - Minor deficiencies do not constitute an immediate threat to the health and safety of the animals.
    - Significant deficiencies present an immediate threat to the health and safety of the animals.
b. Deficiencies from the previous inspection are noted as corrected or repeated on both the checklist and the summary.
c. The PM drafts an inspection summary for review by all team members and then presentation at the meeting.

Semiannual Inspection And Program Review Meeting

a. A separate meeting (if necessary) is held to review the inspections reports.
b. The IACUC reviews each inspection summary. If necessary, the IACUC may vote to determine if certain deficiencies are listed as minor or significant.
c. Members document their approval of the Semiannual Review of Animal Care and Use Program and Inspection of Animal Facilities by providing their signatures. Any member wishing to file a minority report may do so and it is presented to the IO and included in the annual OLAW report. The members who are not present at the meeting are given an opportunity to submit a written minority report.

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

Inspection Report

1. The PM compiles all the deficiencies into an inspection report. Repeat deficiencies are indicated.
    - The PM sends the inspection report to the Director and Assistant Directors for the Department of Comparative Medicine animal facilities.
    - The PM sends the TNPRC inspection report to designated members of the TNPRC Division of Veterinary Medicine and physical plant staff and then meets with the respective personnel to review the deficiency report and note the correction plan and timetable.
    - The PM notifies the PIs responsible for the individual labs indicating any deficiencies and asking for a written response with a correction plan and timetable.
2. All locations must identify a plan of correction, determine the party responsible for overseeing the plan, schedule a timetable for implementation of the plan, and discuss the interim status of ongoing corrective plans. All of these items are added to the report.
3. Plans for the correction of minor deficiencies are monitored by the PM for completion in the manner and by the timetable specified in the plan.
4. Significant deficiencies:

- When an inspection team identifies a significant deficiency, the PM immediately notifies the PI or individual responsible for the lab or facility indicating the significant deficiency and asking for a written response with a correction plan and timetable. Corrective actions or temporary solutions may be enacted to alleviate the immediate threat to the health and safety of the animals until the entire committee can be notified.
- The committee may request additional corrective actions during the semiannual program review meeting. Significant deficiencies that present an immediate threat to the health and safety of the animals must be corrected within 15 days of the determination by the committee, unless otherwise approved by the committee.
- If a plan for the correction of any significant deficiency is not completed in the manner or by the timetable specified in the plan, a meeting of a quorum of the IACUC will be convened and suspension of animal activities in the building or area where the deficiency exists will be enacted as described in SOP 1.6 Investigator Noncompliance and Suspension of Animal Activities.

Departures from the Guide can be identified by various individuals involved in the animal care and use program. All departures are thoroughly researched and justified and presented to the IACUC for review and approval. All departures must be approved by the IACUC and are kept on file in written format. These departures are presented to the IO during quarterly meetings. Any departures from the Guide are included in written format with an explanation as to the reason for the departure. If there are no departures from the Guide, the semiannual report indicates this.

The chair meets with the IO on a quarterly basis and presents the report of the Semiannual Inspection and Program review. The process for developing reports and submitting them to the IO includes review and approval by the full committee of all reports on program review and facility inspections. This is documented in the minutes of the IACUC and through the signature of a majority of the members on a memo of approval. This memo, along with a summary report of program reviews, inspection reports, departures from the Guide, PHS policy and the USDA's animal Welfare Act Regulations and any minority opinions are addressed to the Vice President for Research (IO) and discussed during the quarterly meetings with the IO. These reports are retained on file by the IACUC office for a period of 6 years.

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

Procedures for Reporting

Signs noting that the policy of this animal care facility is that an individual who wishes to express any concern that he/she may have regarding animal care and facilities to higher administration may do so without the fear of reprisal are posted throughout all facilities with contact numbers of the following individuals:

- Chair, IACUC
- Director of the Department of Comparative Medicine (AV)/Chairman of the Division of Veterinary Medicine (AV)
- Executive Director, Comparative Medicine Programs
- Vice President for Research
- Research Compliance Officer (RCO)
- Research Compliance Office hotline

The research compliance office also offers an email address for reporting concerns. An individual may also contact any member of the IACUC. An individual may also send a concern through anonymous means.

It is essential that a reportable activity or condition be brought to the attention of individuals with authority to correct the activity or condition as rapidly as possible while ensuring that the reporting

individual is protected from reprisal as required by law. The identity of the individual may remain private as requested by the reporting individual. An employee making such a claim is protected from reprisal as guaranteed by law. An individual reporting an activity or condition that is found to be false or exaggerated will be advised that such a report is counterproductive to the activities of Tulane University.

Procedures:

1. An animal care and use program comprises the IACUC program, the DCM program, the DVM program, and PIs and staff. Concerns or complaints can be made about any aspect of the animal care and use program and may be reported to one of several individuals and/or departments (RCO whistleblower policy). IACUC members are responsible for referring any concern received to the IACUC chair or the RCO. If the chair is notified she/he contacts the RCO with the initial report. If the RCO receives a complaint she/he notifies the IACUC chair of the issue. The RCO is responsible for assigning a case number and uploading all relevant documents to the research compliance shared folder. The IACUC chair is responsible for oversight of all research compliance issues for the animal care program except allegations made in reference to the IACUC.
2. The RCO notifies the parties involved that an investigation is underway.
3. If animal health or well-being is at risk the IACUC chair contacts the Attending Veterinarian (AV) or assigned veterinarian immediately. The AV or assigned veterinarian investigate immediately and report findings and possible interventions to the IACUC chair. If appropriate, the PI is asked to temporarily stop the work and the animals involved are removed from the study and given routine clinical care until the investigation is completed. If the PI does not agree to halt the study, an emergency meeting of the IACUC is convened and the committee reviews the proposal for suspension of the research.
4. The RCO is responsible for providing reports to the IO.
5. If needed, a subcommittee composed of committee members (must include a veterinarian and a scientific member) is appointed by the Chair to assist with the investigation and resolution of the incident. There may be reported concerns that can be presented to the IACUC without the use of a subcommittee.
6. The subcommittee may meet with the PI involved and/or review relevant documentation. The subcommittee makes recommendations to resolve the incident and to prevent its recurrence. The report is presented at an IACUC meeting for review and disposition.
7. Once the IACUC has agreed on a disposition for the incident the RCO notifies the individual(s) involved and inform appropriate administrators of the decision.
8. The RCO or the IACUC chair can make the initial report to OLAW by phone. Follow-up or final reports to USDA or OLAW is drafted by the RCO, reviewed by the IACUC chair and reviewed and sent by the IO.
9. The RCO is responsible for reporting the incidence to funding agencies if necessary.

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

The IACUC chair, Executive Director of Comparative Medicine, Director of the Department of Comparative Medicine and the Chairman of the Division of Veterinary Medicine meet with the Institutional Official on a quarterly basis. Most recommendations regarding the animal care and use program are conducted during these meetings. Any recommendation that needs to be discussed outside of the scheduled meetings is conducted by setting up an appointment.

- The IO receives reports on any animal concern that is reported and investigated by the IACUC.
- The IO also receives a report of any protocols approved or disapproved by the IACUC.
- The IO receives written recommendations from the IACUC in its semiannual reports.

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

Procedures for Submission of Protocols

1. A current protocol form must be completed and signed by a PI who is a faculty member or have a TNPRC faculty member as the Co-PI in cases of collaboration. An investigator who is not a faculty member must be listed as a co-investigator except for residents in the Tulane Laboratory Animal Medicine Residency Program who may serve as PI.
2. A protocol must be submitted to the IACUC office by the submission deadline in order to be placed on the agenda.

Procedures for Review of Protocols

1. A protocol submitted to the IACUC is placed on the agenda for full review at the next regularly scheduled (monthly) meeting. All protocols submitted undergo full committee review unless the PI requests a review outside of convened meeting, the DVM / DCM submits a breeding holding protocol with a USDA Category B or C, or the submitted protocol is designated a USDA Category B or C (see description of process below).
2. Prior to the IACUC review meeting, an agenda, minutes from the previous meeting, copies of all protocols, and other items listed is distributed to all members by email notification that all materials are available in a shared folder in BOX (cloud). A primary reviewer (and possibly secondary) is assigned to each protocol listed.
3. A quorum of the IACUC is convened and any IACUC member with a conflict of interest may not contribute to the constitution of a quorum for IACUC actions for that particular protocol or other related item scheduled for a vote. If a quorum is not met, the meeting may be cancelled and rescheduled. If the meeting takes place without a quorum, items on the agenda may be discussed but no vote can be taken.
4. After discussion of the protocol by all committee members, the primary reviewer makes a recommendation for *approval, approval with administrative notations, modifications to secure approval, deferral, or disapproval*. A vote from all members present is taken and the status of the protocol is determined by a majority vote unless a voting member calls for full committee review. Any voting member has the opportunity to call for a full committee review. If all members of the IACUC are not present at a meeting, the committee may use Designated Member Review (DMR) subsequent to Full Committee Review (FCR) when modification is needed to secure approval. All IACUC members agree that if they are not present at a convened meeting they agree to abide by the unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol. All members appointed after the approval of the SOP defining the FCR, DMR process are asked to review the SOP and to note their agreement in writing with this provision.
5. Designated reviewers are provided with an identical version of the protocol.
6. For any vote that is not unanimous, a count is recorded, and if necessary, a minority view is documented. Any member who has a conflicting interest in the activity under review is excused from the discussion and vote.

DMR Method for Protocol Review:

A. Protocols for holding and/or breeding submitted from the Division of Veterinary Medicine (DVM) or the Department of Comparative Medicine (DCM) or protocols are categorized as USDA Category B or C are sent per procedures 2-7 below.
B. All protocols other than those noted in #A above are placed for review at the next IACUC meeting unless the PI submits a request for review outside of a regularly convened meeting. If the PI requests this, the following procedures are followed.

DMR Procedure for Protocol Review:

1. The Principal Investigator (PI) must submit the protocol and provide a letter stating the reason why a review is needed prior to the next regularly scheduled meeting.

2. The protocol and letter is forwarded to IACUC members who then in turn notifies the chair whether they think that a) the justification given by the PI is appropriate and the protocol can be reviewed prior to the next meeting and b) that this can be done by a DMR.
3. If any one member calls for FCR, the protocol is placed on the agenda for the next meeting and the PI is notified.
4. If the majority states the request is valid and no member calls for FCR, the chair appoints two members, one of whom is a veterinarian, as designated reviewers. These reviewers are asked to review and submit their recommendations. Designated reviewers are provided with an identical version of the protocol. In order to ensure that reviewers receive the same version, all reviewers are copied on the same email. Reviewers are requested to reply to all with their review comments. If a reviewer does not reply all then the IACUC staff member forwards the comments to the other reviewers. If there are subsequent versions of the protocol, one email is sent to ensure the all reviewers receive the same version for review. The reviewers must be unanimous in their decision. If one reviewer requests a modification(s), the other reviewers are made aware of the requested modification(s) and must agree to the modification(s). It is the responsibility of the IACUC office to make sure that the other reviewers are made aware of the modifications requested and document their agreement or disagreement of the requested modifications. A designated reviewer has the right to approve, require modifications or refer the protocol to full review. The designated reviewer does not have the right to withhold approval; in such cases the protocol is referred to full committee review. Any committee member may request to be a designated reviewer or submit comments after reviewing the protocol. All comments are forwarded to the designated reviewer(s).
5. The designated reviewers' approval is equivalent to full committee review approval.

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

All changes to a proposed research protocol must be submitted to the IACUC for review and approval prior to instituting the proposed change using the amendment form. Criteria to determine what is considered a significant change that could potentially undergo IACUC review as a minor amendment, as well as what is considered a significant change to be sent to the IACUC for review, are documented in SOP 1.4 Review Process for Proposed Animal Activities and Modifications to Ongoing Activities.

A. Significant changes that may undergo review as minor amendments include, but are not limited to, changes in:
    a. anesthesia, analgesia, sedation, or experimental substances;
    b. euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals; and
    c. duration, frequency, type, or number of procedures performed on an animal.
    Amendments are reviewed by the chair and those determined to be minor are sent to a veterinarian for review. If the veterinarian does not deem it to be minor, it is sent to the IACUC for review and steps outlined under B. are followed, including the opportunity for each member to vote on whether the amendment can be reviewed by a designated member (DMR) or should undergo committee review (FCR). If the veterinarian agrees that the amendment is minor, then s/he becomes the designated reviewer.
B. Significant changes to be sent to the IACUC for review include, but are not limited to, changes:
    a. from nonsurvival to survival surgery;
    b. resulting in greater pain, distress, or degree of invasiveness;
    c. in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
    d. in species;
    e. in study objectives;
    f. in Principal Investigator (PI); and
    g. that impact personnel safety.

1. A copy of the amendment, the protocol with previous approved amendments, and other documents deemed pertinent to the request are sent to committee members by email or provided in a shared folder. Each committee member is asked to decide whether the amendment can be reviewed by a designated member (DMR) or should go to full committee review (FCR).
2. Any committee member may request to be a designated reviewer or submit comments after reviewing the amendment. Comments may be sent to the PI for clarification prior to review by the designated reviewer or forwarded to the designated reviewer.
3. If any member calls for FCR, the amendment is scheduled for review at the next scheduled meeting and the PI is notified.
4. If no member calls for FCR the chair appoints one or more members of the committee as the designated reviewer(s). The reviewer(s) should submit his/her recommendation in a timely manner. A designated reviewer has the right to approve, require modifications or refer the amendment to full committee review. The designated reviewer does not have the right to withhold approval; in such cases the amendment is referred to full committee review.

The designated reviewer approval has equal validity to full committee review approval and does not require subsequent approval or notification by a convened meeting. All amendments approved within a three-year period after the protocol approval date are bound to the protocol they amend. After three years, all procedures and aspects approved via amendment anticipated to remain a component of the study must be included in the renewal protocol. It is the responsibility of the PI to notify support agencies and collaborators of any modifications to their original protocol.

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:

The investigator is notified by email of the review outcome:

1. No action is required from investigators whose protocols are approved as submitted.
2. Investigators, whose protocols receive approval with administrative notations, must provide an updated protocol with the notations highlighted, underlined or bolded or provide approval of administrative changes made by the IACUC office. The IACUC chair checks the notations for completeness and accuracy.
3. Investigators whose protocols receive modifications to secure approval must provide a revised protocol with the modifications highlighted, underlined, or bolded. The revised protocol must be received in the IACUC office within 3 months from receipt of the disposition letter. If a protocol has not been resubmitted with revisions within this period the protocol is considered voided and must be resubmitted for full committee review. The primary reviewer(s) receives the revised version of the protocol and ensures all modifications have been completed and then assigns an approval for the protocol. If the primary reviewer decides that not all of the modifications have been adequately addressed it is returned to the IACUC office with a request for further modifications. This request is sent to the PI who must address the modifications and return a revised protocol.
4. Investigators whose protocols are not approved receive a written notification describing the reasons for this decision. If the committee allows a revision of the protocol, the revised version would be reviewed at a convened meeting.

Once a protocol is approved, a notification of approval is sent to the PI and appropriate personnel by email. The chair meets quarterly with the IO and provides minutes with the outcome for all protocols. All protocols are entered into the animal records database with a precise documentation of their history. Appropriate personnel have access to approved protocols and amendments through a shared folder. It is the responsibility of the PI to notify support agencies and collaborators of any modifications that are required to secure approval.

Investigator Appeals - In the event an investigator disagrees with the decision of the committee, the following options are available:

- Submission of a revised protocol or amendment
- Written appeal to the committee
- Written appeal to the IO

The IO may request that the full committee reconsider the protocol or amendment. However, the decision of the committee, in review of appealed protocols initiated by the investigator or the IO is final.

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:

Continuing Review of Animal Activities

1. To comply with continuing review requirements, the IACUC office generates annual review forms approximately 60 days prior to the approval anniversary date every two weeks for protocols that utilize USDA covered species or as required by specific funding agencies. PIs are required to complete the annual review and return the form to the IACUC office prior to the first and second anniversary date of their protocol approval. All annual reviews undergo an administrative review by the IACUC office prior to the first and second anniversary date of the protocol approval. They are then placed on the meeting agenda to inform the IACUC and present them with an opportunity for discussion. Any annual review reporting unexpected mortality or morbidity is assigned to a reviewer for presentation at a convened meeting of the IACUC.
2. For each protocol that was approved three years ago, an email is sent to the PI starting at 120 days prior to the expiration of the protocol. The PI is asked to indicate the status of the protocol and his/ her plans for renewal. Additional notices are sent as reminders.
3. PIs are required to submit a completed protocol form every three years for all studies. The IACUC completes a three-year *de novo* review following same review and approval process as an initial submission.
4. Completed Annual Review forms are added in the protocol files according to record keeping requirements.

Monitoring Ongoing Activities

IACUC Office

Expiration Reports: The IACUC office reviews protocols that expire in the next two months that have animals assigned to the protocol. The PI is notified by email or phone call as to the status of the protocol. The PI is informed that animals assigned to a protocol set to expire will be placed under the care of the DCM or DVM. This process ensures that no animals are left on an expired protocol. If the PI fails to have a renewal approved, transfer the animals, or complete the study by the expiration date the IACUC office notifies the DVM or DCM that no experimental procedures can occur for that particular study. The PI will no longer have access to the animals until a protocol is approved. The veterinary and animal care staff provide clinical care.

Post Approval Monitoring Program (PAM): The purpose of the PAM Program is to provide a continuous review of the Principal Investigator's IACUC-approved protocols and amendments to ensure that research and teaching activities involving live vertebrate animals are conducted in accordance with all applicable regulations and are consistent with the PI's protocol. The goal of PAM is to work with, and in support of, research staff members and to confirm accurate and consistent protocol performance in a collegial and unobtrusive manner. The intent of PAM is to help maintain compliance so that the scientific work may continue without disruption for noncompliance issues.

The PAM program applies to all IACUC approved protocols using animals in research and teaching at all Tulane facilities. Due to the Department of Veterinary Medicine's role in conducting all procedures at the Tulane National Primate Research Center, the monitoring is different between the TNPRC and the New Orleans' Campuses (NOC).

TNPRC - All animal research support activities are captured prior to the activity on the TNPRC research support schedule. Random research support schedule checks are performed on a weekly basis. A minimum of 10% scheduled research procedures are randomly selected from the upcoming week's schedule. The process involves comparing scheduled procedures to the approved procedures in the protocols and amendment. In performing the check, it is possible to uncover a deviation from approved procedures with the current request. An investigator may be contacted to clarify information. If the check shows that there is any change from the approved protocol or amendment, the PI is asked to file an amendment to include the changes. A PI may also have to reschedule a procedure if the time point is not correct or cancel a procedure until an amendment for approval of procedure(s) is obtained. In addition, the PM monitors the Mathematica tool for approved procedures which is described below under 2) Procedure Verification Tool.

NOC - Research procedures are monitored both in the DCM facilities and the outside labs. The process involves comparing the procedure being performed at the time of monitoring to the approved protocol /amendments. The interaction with the research staff during the monitoring also queries their knowledge on key components of animal care and use (reporting animal welfare concerns, increases in morbidity and mortality, changes to protocol). If the comparison results in a deviation from the approved procedures the PI is asked to submit an amendment and stop the procedure until the amendment is approved. In addition, PAM of new procedures, where the IACUC has requested additional oversight, is conducted. Protocols involving major survival surgery and pain category E are monitored more frequently.

Department of Comparative Medicine - New Orleans Campuses
Veterinarians and DCM animal care staff provide additional post approval monitoring by being involved in many of the animal procedures post IACUC approval. Animal care technicians provide information regarding animal health on a daily basis and any health or welfare issues are brought to the attention of the DCM. The veterinarian, assistant directors and/or supervisors also monitor animals in the facility on a regular basis. All changes to research protocols via the amendment process are sent to the attending veterinarian for review.

Division of Veterinary Medicine - TNPRC
The post approval monitoring program at the TNPRC is comprised of several elements including animal research procedure scheduling, veterinary oversight, regular animal health monitoring of all animals assigned to research, oversight by the Unit of Compliance and Training, and use of computational compliance tools.

Animal research procedure scheduling
Schedule requests are evaluated using several methods to assist in maintaining compliance as part of the post approval monitoring program.

Weekly review of animal procedure schedule, blood withdrawal volumes, and body weight
Advance scheduling with the Division of Veterinary Medicine is a requirement for all animal research procedures. Schedules are created in a weekly format and a more detailed daily format. The schedules are disseminated to all animal research areas. In addition to the computational methods for procedure verification described below, veterinarians review schedules of animal procedures the week prior to scheduled activity to help assure that they comply with the approved IACUC protocol. Weekly schedule review is also performed by IACUC administration using a computational tool (see below). Monthly blood volume collection limits for all animals on the following week's schedule are calculated using computational methods (see below). If a requested blood volume exceeds IACUC limits, the PI is notified that the volume will be reduced to comply with the policy.

Veterinarians and veterinary technicians review requested animal procedures in the week prior to the procedure. New or unusual procedures noted on the upcoming week's research support schedule are brought to the attention of the assigned veterinarian for review. The IACUC office assists the DVM with post approval monitoring of scheduled research procedures by: 1) On a weekly basis the PM provides a check on at least 10% of scheduled procedures to determine consistency with approved activity. The result of this

increased scrutiny may involve cancellation of a procedure or getting an amendment filed to get an activity approved/rescheduled, 2) Implementation of software that automatically monitors the schedule for procedures not approved on a protocol. A daily report is sent to the PM, which shows if a scheduled procedure is not approved. The IACUC office maintains a spreadsheet with approved procedures, and this is updated as protocols are approved. This spreadsheet provides the information that that program uses to note if a procedure is approved or not. Any unapproved notification is followed up by the PM, 3) The PM also provides additional oversight for PIs that have shown a pattern of inconsistencies. Once an inconsistency is identified, the PM works with PIs to come to an appropriate resolution, and 4) Monitors the animal records system (ARS) for accuracy and follows-up with the Division of Veterinary Medicine staff member entering the data.

Veterinary oversight

A veterinarian is assigned to each IACUC protocol at the time of approval. The assigned veterinarian is responsible for communication with principal investigators, providing oversight of research procedures, and providing clinical care to animals. Veterinarians and animal care staff in the Division of Veterinary Medicine (DVM) provide additional post approval monitoring by being involved in essentially all animal procedures performed at the TNPRC. For studies that use mice, all PIs and/or staff are trained and proficiency assured by a veterinarian prior to performing any procedures. All changes to research protocols via the amendment process are communicated to the assigned veterinarian.

Regular animal health monitoring of all animals assigned to research

In compliance with IACUC and Division of Veterinary Medicine policy, after NHP are assigned to research protocols, they must have a physical examination by a veterinarian, complete blood count and serum chemistry performed at minimum prescribed frequencies to monitor health status. The results of these diagnostic procedures are contained in the TNPRC animal records database.

Quality assurance inspections of activities and facilities

QA specialists in the Division of Veterinary Medicine monitor training and compliance of animal care staff and the maintenance of animal facilities through monthly inspections, which are documented. QA Specialists provide training to both new and experienced animal care personnel.

Computational (Mathematica) compliance tools

1. Available Blood Volume (ABV) Tool

The purpose of this tool is to provide an efficient means for veterinary medicine staff to monitor requests for blood sampling ensuring that the volume does not exceed acceptable policy parameters (12ml/kg in a 4-week period).

2. Procedure Verification Tool

The procedure verification tool is used as a form of additional verification to minimize the risk of unapproved activities being performed on an approved IACUC protocol. The IACUC PM monitors the report that alerts if unapproved procedures are placed on the animal procedure research support schedule, which is administered by the Division of Veterinary Medicine and contains all activities that are requested to be performed in animals at the TNPRC. This tool provides a daily assessment based on planned activities for the next 7-10 days, which are contained in the animal procedure research support schedule. The program allows the schedule to be checked against a running spreadsheet of approved protocols and cross referenced to an IACUC approved procedure spreadsheet associated with the protocol. If a noncompliant activity has been scheduled, the PI is contacted to prepare an amendment for submission. Depending on the timing of the procedure, the activity may be cancelled to allow appropriate time for amendment approval. The veterinarian assigned for oversight of the project is informed as another level of monitoring.

3. Weight Monitoring Tool

This tool utilizes the weight file extract from the Animal Records System done as part of the ABV monitoring tool. For each animal scheduled to be accessed in the coming weeks, a table of weights and a graph are created. An alert threshold is set at a default of 15% change (increase or decrease) in body weight; however,

this threshold can be modified. Within the table, a change that is above or below the set threshold is highlighted in yellow. This tool is invaluable to the veterinarians as they monitor the health and well-being of the animals on protocols they are responsible for.

10) Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

The IACUC is empowered to suspend a project if it finds noncompliance with the PHS Policy, *Guide*, Assurance, or violations of the Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and with the suspension vote of a majority of the quorum present supporting the decision.

1. Once the IACUC suspends an animal activity, the Institutional Official (IO), in consultation with the IACUC and the Research Compliance Officer (RCO), will review the reasons for suspension and take appropriate corrective action.
2. Either the chair or the RCO will make an initial report of suspension to OLAW. Final reports for suspension are sent by the RCO through the IO. If the suspension involves a species covered under the Animal Welfare Act the RCO will submit a report to the USDA.
3. The PI or responsible party whose animal activity has been suspended will be notified in writing of the decision and any description and timetable for corrective action.
4. The DVM or DCM will be notified, and all scheduling and support of activities beyond routine husbandry and clinical care of the animals will cease until further notice.
5. The PI must submit a new protocol for review and approval by the IACUC before animal activities can be resumed.
6. Once an animal activity is reviewed and approved by the IACUC to resume after suspension, the IACUC chair will notify the IO.

E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:

The Tulane University Compliance Steering Committee oversees the work of several committees including the Environmental Health and Safety Operations Committee which is empowered to review, evaluate, and make recommendations for policies, procedures, and guidelines related to environmental health and safety at Tulane University. The Office of Environmental Health and Safety (OEHS) is charged with compliance assessment and dissemination of environmental and occupational health and safety policies and practices campus-wide including preparation and dissemination of the University's Environmental Health & Safety (EHS) Policies and Procedures Manual (http://tulane.edu/oehs/upload/PPMFullWebA.pdf). Departmental Safety Representatives (DSRs) act as liaisons between their departments or units and the OEHS in disseminating safety information and addressing safety concerns within their department or unit. Other committees involved in the occupational health and safety program include the Control of Occupational Exposures Committee (COEC), the Radiation Safety Committee, and the Institutional Biosafety Committee (IBC). These Committees, OEHS, and departmental Designated Safety Representatives (DSR), in cooperation with all supervisors/principal investigators, faculty, staff, and students, work to ensure compliance and to create a safe and healthy workplace.

Tulane University's occupational health and safety program, as it pertains to personnel who handle or have substantial contact with animals in research and teaching, relies on administrative support and interactions among several institutional elements, including the research program (as represented by the principal investigator), the animal care and use program (as represented by the Department of Comparative Medicine (DCM), Division of Veterinary Medicine (DVM), and the IACUC), the environmental health and safety program (as represented by the Office of Environmental Health and Safety - OEHS), the Office of Biosafety (OBS), and the TNPRC Occupational Health Clinic.

Control and prevention strategies
Members of the OEHS and the OBS review IACUC protocols to identify chemical, physical, and biological hazards and assess the risks. OEHS and OBS evaluate and periodically inspect work areas to ensure the appropriate design and operation of the facilities, including the proper use of safety equipment (such as the certification that fume hoods or biological cabinets are operating properly, or that laboratories are properly designed for the required biological safety level when working with particular biological agents). Processes and standard operating procedures (SOPs) to be used in the protocols are reviewed by OEHS and OBS to ensure that the hazards are handled appropriately with respect to proper engineering and work practice controls. The required personal protective equipment (PPE) to be used by the researchers as well as the animal care staff is also reviewed. If special equipment or safety practices are needed, this is discussed with the researcher as well as the animal care staff.

Researchers and animal care staff receive safety training and are expected to maintain good personal hygiene. Signage (as identified in the hazard review) and training are used so that the researchers and animal care staff become knowledgeable about the hazards in their work environment and understand the proper selection and use of PPE. The researchers and the animal care staff are expected to follow proper procedures and to use the PPE provided.

Hazard identification and risk assessment
Hazards identified upon submission of an IACUC protocol/amendment are reviewed by the OEHS and the OBS. The OEHS and OBS are involved in the assessment of risks associated with hazardous activities and in the development of procedures to manage such risks, including site inspections and review of any reported potentially hazardous conditions or "near miss" incidents. PIs who conduct and support research programs that involve hazardous biological, chemical, or physical agents (including ionizing and nonionizing radiation) are responsible for identifying the hazards associated with the protocols and implementing appropriate safeguards as recommended by OEHS and OBS.

Potential hazards, such as animal bites, chemical cleaning agents, allergens, and zoonoses that are inherent in or intrinsic to animal research are identified and evaluated. Risks associated with the experimental use of animals are reduced by engineering controls (ventilated cage units, ventilated bedding dumping stations, biosafety cabinets, facility containment), administrative controls (training, work practices), and use of personal protective equipment.

The extent and level of participation of personnel in the occupational health and safety program is based on the hazards posed by the animals and materials used; on the exposure intensity, duration, and frequency; on the susceptibility of the personnel; and on the history of occupational illness and injury in the particular workplace.

Facilities, equipment, and monitoring
Washing and showering facilities are available as are emergency eyewash units and safety showers. Where possible, facilities, equipment, and procedures have been designed, selected, and developed to provide for ergonomically sound operations that reduce the potential for physical injury to personnel (such as might be caused by the lifting of heavy equipment or animals and the use of repetitive movements). Biological safety cabinets and chemical fume hoods are used to reduce exposure to biological and chemical agents respectively and are certified annually. Fume hoods are equipped with airflow monitoring devices and alarms. Tulane University uses the CDC/NIH publication Biosafety in Microbiological and Biomedical Laboratories (BMBL) as the basis for recommended practices and procedures, safety equipment, and facility requirements for working with hazardous biological agents and materials. Also the publication entitled Prudent Practices in the Laboratory is used for recommended practices and procedures, safety equipment, and facility requirements when working with chemical hazards.

Experimental animals are housed so that potentially contaminated food and bedding, feces, and urine can be handled in a controlled manner (ventilated cage units). Facilities, equipment, and procedures are provided for appropriate bedding disposal (ventilated dumping stations). Access to animal care areas is limited to authorized personnel.

Laboratories are marked with signage indicating the types of hazards found in the lab, emergency contact information, and authorized admittance only.

The OEHS is responsible for assessing exposure to potentially hazardous chemical and physical agents where the possibility of exceeding permissible exposure limits (PELs) exists and will conduct personal exposure monitoring as needed.

Personnel training
Operational and day-to-day responsibility for safety in the workplace resides with the laboratory or facility supervisor (e.g., PI, animal facility supervisor, or veterinarian).

Research personnel are provided with standard operating procedures developed by the PI for conducting their duties, understanding the hazards involved, and implementing required safeguards. Animal care personnel are trained to understand the hazard potential and how to protect themselves.

As appropriate to the risk, personnel are trained on zoonoses and allergies (by facility veterinary staff), chemical safety (by OEHS), biological hazards (by OBS), physical hazards (by OEHS, including those hazards related to radiation and noise), unusual conditions or agents that might be part of experimental procedures (as deemed necessary by OEHS and the OBS, including the use of genetically engineered animals and the use of human tissue in immune-compromised animals), handling of waste materials (by OEHS), personal hygiene (by OEHS, the PI, and veterinary staff), and other considerations (as determined by OEHS and OBS, e.g., precautions to be taken during personnel pregnancy, illness, or decreased immuno-competence).

Supervisors/PIs are primarily responsible for ensuring that employee training is provided and documented; ensuring that work areas are inspected and meet safety requirements; ensuring that workers use safe work practices and procedures; and ensuring that compliance paperwork (including annual chemical inventory, SOPs for labs, PPE and respiratory assessments, quarterly inspection documentation, hazard assessment forms, etc.) is completed. During semiannual laboratory inspections by the IACUC, the inspection team examines the room for possible hazards (e.g. overfilled sharps containers, unsecured gas cylinders), inspects fume hood and biological safety cabinet certification certificates, and verifies that training has been documented. Deficiencies are noted in the inspection report and presented at the semiannual inspection and program review meeting as outlined in Section D.2.

Personal hygiene
All research personnel and animal handlers maintain a high standard of personal cleanliness. Tulane supplies clothing suitable for use in the animal facility and laboratories in which animals are used. Disposable gloves, masks, head covers, coats, coveralls, and shoe covers are used in some circumstances. Personnel are directed to wash their hands and change clothing as often as necessary to maintain personal hygiene. Outer garments worn in the animal housing areas are not worn outside the animal facility. Personnel are not permitted to eat, drink, use tobacco products, or apply cosmetics in laboratories or animal housing areas.

Animal experimentation involving hazards
In selecting specific safeguards for animal experimentation with hazardous agents, careful attention is given to procedures for animal care and housing, storage and disbursement of the agents, dose preparation and administration, body-fluid and tissue handling, waste and carcass disposal, and personal protection.

Written policies governing experimentation with hazardous chemicals have been developed as part of the University's Chemical Hygiene Plan, which is found in the EHS Policies & Procedures Manual. The Radiation Safety Manual and the University's EHS Policies and Procedures Manual contain written policies on physical agents such as ionizing and non-ionizing radiation and laser use. The OBS provides written policies on biological hazards and provides oversight of "select agents and toxins." OEHS and OBS review IACUC protocols for the safe use of hazardous materials and collaborate with the researchers and animal care

personnel, both to provide technical support and training, and to ensure the facilities are adequate for the safe conduct of the research.

Exposure to hazardous agents associated with the experimental use of animals has been reduced by implementing engineering controls (ventilated cage units, ventilated bedding dumping stations, biosafety cabinets, fume hoods, facility containment, HEPA filtration), administrative controls (training, work practices), and use of personal protective equipment. Personnel exposure to waste anesthetic gases is limited by using various scavenging techniques (vacuum system, local exhaust ventilation) or a chemical filtration system. OEHS conducts personal exposure monitoring to waste anesthetic gases and other hazardous chemicals periodically or upon request.

Personal protection
Tulane provides personal protective equipment (PPE) such as respiratory protection, hearing protection, face shields, etc. and protective clothing (such as shoe covers, gowns, chemical resistant gloves) as needed. If deemed appropriate, personnel are required to shower when they leave the animal care, procedure, or dose-preparation areas. Protective clothing and equipment are not worn beyond the boundary of the hazardous-agent work area or the animal facility.

When respirators are needed, the employee's department or unit is responsible for obtaining medical clearance in order to wear a respirator. Once medical clearance has been obtained, OEHS provides respirator fit-testing and training on respiratory protection in accordance with the OSHA Respiratory Protection Standard.

Medical evaluation and preventive medicine for personnel (including immunizations, vaccinations, and procedures for reporting and treating bites, scratches, and injuries.)
All personnel are instructed to notify their PI or supervisor about any occupational injuries (including bites or scratches), potential or known exposures and suspected occupational illnesses including allergic reactions. Injured or ill personnel at the Uptown and Downtown campuses are directed to complete a First Report of Occupational Injury/Illness and are directed to the Worker's Compensation Program Coordinator who will assist them in seeking medical attention. In the event of an animal bite, scratch, injury or illness, affected employees may go to the nearest local emergency room for 24/7 care. Under Louisiana law the injured/ill person may go to their physician of choice. If there is no preferred physician, the Worker's Compensation Coordinator will assist them in finding appropriate medical care at an established list of clinics or emergency rooms in the area. If an infectious disease is involved, the injured/ill person may be seen by a Tulane Infectious Disease physician who will examine the patient and provide prophylaxis and an appropriate treatment regimen.

Tulane's Animal Handler Health Surveillance (AHHS) Program is designed to protect Tulane personnel (including employees and students) from occupational exposure to conditions that may result in animal-related illnesses. Personnel having significant exposure to animals are required to fill out the Risk Assessment and History Form (RAHF) and complete any medical evaluation deemed appropriate. OEHS ensures that personnel who are required to complete a RAHF are notified of the requirement. OEHS provides the DCM with an up-to-date list of individuals who have completed the RAHF requirement. Before providing access to the animal facilities, the DCM verifies that the individual has completed the RAHF requirement, completed orientation training, and has been added to an approved IACUC protocol. Individuals who are missing any of these three requirements are not provided access to the animal facility.

The current AHHS program includes three distinct groups of personnel who are required to participate in the program: 1) animal handlers, caretakers, and researchers who have frequent or substantial contact, 2) animal researchers who do not have substantial or frequent animal contact, and 3) other support personnel (maintenance, security, etc.) and visitors.

As part of the AHHS program, animal handlers, caretakers, and researchers who have frequent or substantial animal contact must complete a Risk Assessment & History Form (RAHF) prior to working with animals and must have periodic medical evaluations, if deemed necessary. The RAHF indicates how the person's position involves contact or exposure to animals, the types of animals involved, the frequency of exposure, the health

history of the person including prior tetanus or rabies vaccines, and recommendations for additional immunizations and screening. The RAHF is reviewed and if additional medical surveillance is required, the person is notified and is advised to see a medical practitioner. If determined medically necessary by a licensed medical practitioner, periodic medical evaluations are done to assess the continued health of these personnel.

Researchers and visitors who do not have substantial or frequent animal contact, or personnel such as campus maintenance employees who do not directly handle the animals must also complete the RAHF as described above. The RAHF is reviewed, and they are strongly advised to complete any recommendations for further medical evaluation if deemed necessary. They are informed of conditions of concern and of the risks and hazards associated with animal research. This group is classified as visitors.

All Institutional Animal Care and Use Committee (IACUC) protocols are reviewed to ensure that all personnel with animal contact participate in the AHHS program. All Tulane personnel listed on an IACUC-reviewed protocol are provided information on the AHHS program by the Office of Environmental Health and Safety (OEHS). Principal investigators are responsible for ensuring that all personnel involved with their IACUC-reviewed project are given AHHS program information. Principal investigators and their personnel who do not respond to written requests from OEHS to participate in the AHHS Program will not be allowed to enter or work with animals in animal housing facilities.

The RAHF is reviewed and follow-up is initiated (as necessary) with the individual based upon medical history noted in the completed form, the type of animal contact, screening, and immunizations required by the program. If a question in the History section of the RAHF is answered YES and if the condition is related to animal handling, if zoonosis surveillance is needed, or if work involves animals or tissues experimentally infected with human pathogens, then additional follow-up may be needed. The AHHS Program's immunization and screening is noted as follows:

Immunizations and screening

- Tetanus immunization is highly recommended for all individuals with animal contact. A booster shot is needed if it has been 10 or more years since the previous tetanus immunization. The TNPRC Occupational Health department offers tetanus vaccinations to all animal care staff, PIs and lab personnel on that campus. The Department of Comparative Medicine offers the vaccination to all animal care staff.
- The Hepatitis B vaccination is required to be offered to individuals who work with animals/animal tissues that are known to be genetically altered with human or non-human primate genes or tissues that are known to carry the hepatitis B virus (HBV). Refusal to accept the vaccine must be provided in writing.
- Semi-annual tuberculosis (TB) screening is required for individuals who handle non-human primates or those who are working with animals or tissue infected with Mycobacterium species.
- Rabies immunization is recommended for individuals who handle with dogs, cats, or ferrets. A titer will be required if previously vaccinated.
- Other immunizations and screenings may be necessary based on the species of animal and type of work.
- It is recommended that all personnel review their allergy status on an annual basis with a physician or other licensed healthcare provider.
- All University personnel who work with animals as indicated in IACUC protocols are required to participate in the AHHS program. PI's are responsible for ensuring that all personnel involved with their IACUC-reviewed protocol are given AHHS program information.

TNPRC Special Precautions

Based on the occupational health risks associated with working with nonhuman primates, additional precautions are taken at the Tulane National Primate Research Center (TNPRC) to ensure adequate prevention and injury response strategies. Employees are given annual or semi-annual tuberculin skin test depending on their level of exposure to nonhuman primates. For health concerns and exposures, employees are seen in the TNPRC Occupational Health Clinic (OHC) and referred to the appropriate physician if needed. Many injuries can be treated with first aid, evaluated and followed up by the Occupational Health Nurse (OHN). Physician coverage is provided by the local occupational health clinics or emergency rooms as needed. A Tulane

Infectious Disease Specialist works closely with the onsite OHN in the event of exposures to infectious diseases. If an injury occurs, the employee follows the instructions for cleaning the wound per injury protocols. A "First Report of Injury" form is completed by the employee or supervisor and forwarded to OEHS by the OHN, and a blood sample is drawn. The employee is then put on a schedule to have a second sample drawn in three to four weeks. Prophylactic medication is provided according to standing orders provided by a Tulane Infectious Disease Specialist. The animal involved in the incident is bled for a serum sample and swabs are taken for culture. The samples from the human and animal are sent to the B-virus Reference Laboratory. Viral culture swabs are collected from nonhuman primates by a veterinarian who performs a physical examination at the time of sample collection. Any abnormal examination findings are noted in the animal's record, on the accident report, and relayed to the nurse. Veterinarians review animal health records to ascertain the animal's viral status and experimental infection status. The serum is checked for antibody to B virus within 48 hours. Culture results are reported to the nurse within 5 days. Depending on the severity of the injury, the employee may be referred to the local physician or to one of the hospital emergency facilities in the area.

OEHS/Workers' Compensation is also notified. Physicians at local occupational health clinics and emergency facilities have received a packet of information on B virus and contact numbers for consultation. Employees are advised to report any symptoms that can be related to B-virus infection to the OHN.

All employees are trained in emergency response procedures within their departments. SOP 5.1 Personnel Injury Procedures; 5.3 Procedures for Employees Following Possible B Virus Exposure; and 5.4 Procedure for Employees Following Possible Simian Immunodeficiency Virus Exposure, are in place post injury or possible exposure. The OHN is on-call 24/7 in the event of injuries or exposures and can access Tulane Medical Center physicians or the local emergency room after hours for coordination of treatment.

TNPRC employees are encouraged to become CPR certified and there are seven defibrillators (AEDs) on site in the event of an emergency. For work in ABSL3/BSL3 containment areas, employees are fit tested for respirators by OEHS personnel.

F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.

Completed Facility and Species Inventory table provided (see Part X.).

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

TNPRC
Animal Care Technicians, Veterinary Technicians, Behavioral Management Technicians and other Animal Care Staff

On the first day of hire, new animal care staff receive training via PowerPoint presentations in occupational health, proper use of PPE, IACUC functions, overview of NHP behavior and regulations, laws and policies that apply to the care and use of animals in research including a section on the IACUC which provides specific training on the use of the Three R's to achieve the goal of humane experimental techniques, research or testing methods that minimize the number of animals required to obtain valid results and minimize distress, and how the institution assists with consideration of the Three R's prior to protocol approval. The occupational health nurse provides training in NHP zoonotic disease transmission and completes an animal handlers health assessment form. After the first day of training is completed, animal care staff enters a six-week training program focused on the specific areas applicable to their job.

The six-week training program is provided by Animal Care Technician Supervisors, Quality Assurance specialists, Resource Manager and veterinarians. The training program is coordinated and administered by the Unit of Compliance and Training and the Division of Veterinary Medicine Training Committee.

In addition to this training, new Animal Care Technicians receive a five-week course from the Unit of Behavioral Management. Topics covered are as follows: recognizing and interpreting normal and abnormal behavior, causes abnormal behavior, how to implement environmental enrichment and the rationale behind it, methods and responsibilities associated with social introductions, appropriate demeanor around caged primates, and overviews of positive reinforcement training and breeding colony behavioral management. Sessions are followed with quizzes. Documentation of training is kept in each employee's personnel file in the Division of Veterinary Medicine.

As a supplement to the Division of Veterinary Medicine Training Program, the Purina Laboratory Animal Training Course (Purina Home Course) is required for all Animal Care Technicians. All new hires are required to complete the course within the first six months of employment.

AALAS Certification

AALAS certification at all three levels is encouraged and facilitated through the Division of Veterinary Medicine. The DVM currently has 28 ALAT, 5 LAT, and 4 LATG certified technicians. Additionally, the DVM has one Manager that completed the Certified Manager of Animal Care (CMAR) program and another currently enrolled in the CMAR program. Classes following the ALAT Training Manual are administered by members of the Division of Veterinary Medicine Training Committee. These classes are taught by veterinarians, AALAS certified technicians, and management staff. An incentive program is in place for AALAS certification.

Experience

Personnel in animal care are stratified across different experience levels in each of their particular areas of interest. Animal Care Technicians with little or no experience enter the program as Animal Care Trainees. Defined levels of responsibility and experience are required for promotion to the next level. Individuals are hired into positions corresponding with their level of experience. Animal Care Technician positions include Animal Care Trainee, Animal Care Technician 1 (ACT1), ACT2, ACT3, ACT4, ACT Supervisor, and Manager Animal Care. Behavioral management and Veterinary technicians have similar experience/responsibility advancement. A copy of animal care job descriptions will be available for site visits. Currently, the Division of Veterinary Medicine has the following active animal care staff positions:

Position	**Number of Personnel**
Animal Care Technician (ACT)	
ACT Trainee:	14
ACT1:	4
ACT2:	19
ACT3:	12
ACT4:	6
ACT Supervisor:	14
Behavioral Management Technician (EET)	
BMT1:	1
BMT2:	2
BMT3:	4
Veterinary Technician (VT)	
VT1:	0
VT2:	1
VT3:	3
VT4:	5
VT Supervisor:	1

Compliance

Quality Assurance Specialist:	2

Management staff

Assistant Director for Animal Resources:	1
Breeding Colony Program Manager:	1
Resources Manager:	1
Behavioral Manager:	1
Animal Colony Epidemiologist:	1
Manager, Animal Care:	2

Continuing Education

The continuing education program has several components. These include monthly presentations at Division of Veterinary Medicine staff meetings, weekly supervisor meetings, wet labs to improve proficiency in technical procedures, and targeted training for groups or individuals as specific need arises. The Office of Biosafety provides select agent training and Tulane's Occupational and Environmental Health and Safety (OEHS) Department provides annual blood borne pathogen training. Attendance at these continuing education sessions is mandatory for animal care staff. Documentation of attendance is maintained in the Office of the Chair in the Division of Veterinary Medicine and/or the Office of the Head of the Unit of Compliance and Training.

At least annually, Animal Care Technicians are evaluated for proficiency in the required elements of their job description by Quality Assurance Specialists in the Unit of Compliance and Training. If the assessment concludes that retraining is necessary, a personalized retraining program is administered by personnel in the Unit of Compliance and Training. The training may take the form of a classroom PowerPoint, a hands-on wet lab, or both.

The Division of Veterinary Medicine reviews Animal Husbandry and Veterinary Care SOPs at weekly meetings with Animal Care Supervisors. Supervisors then review this information with their assigned staff after each meeting. Documentation of training is available and maintained at the Division of Veterinary Medicine administrative office.

The IACUC has approved a training-specific animal use protocol (#P0009R3-3436 TNPRC Laboratory Animal Medicine Training) to allow animals maintained on breeding and holding protocols to be used to train animal care personnel on common, noninvasive, or minimally invasive procedures. These hands-on, wet lab sessions are administered by the Division of Veterinary Medicine Training Committee. The training includes all species maintained at the TNPRC: NHPs, mice, rats, and rabbits. This protocol also allows veterinarians or veterinary students to practice clinical techniques on animals prior to euthanasia as nonsurvival exercises. The wet labs are offered year round on a rotating basis. Before participating in wet labs, animal care staff must have at least 6 months experience, have a recommendation from their supervisor, and have completed the didactic component of the training (PowerPoint presentation and lecture). The didactic and wet lab sessions are taught by senior technicians and veterinarians. Participation in these sessions is documented.

Documentation of training activities is kept in both hard copy and electronically in a training spreadsheet.

Senior management, animal care technicians, behavioral management technicians and veterinary technicians may attend state and national AALAS meetings. Attendance in most cases is allowed for those that are serving as officers of the state or national organization or those that present either a poster or oral presentation. Funds for meeting attendance are a line item in the budget for the Unit of Compliance and Training.

Research Staff

The IACUC approves animal care and use protocols only after assuring that individuals performing procedures in animals have been trained to do so. The IACUC protocol submission form requires information from investigators regarding responsibilities and training of research staff.

The Division of Veterinary Medicine works closely with staff and researchers on every project involving the use of animals. The Center requires all personnel involved in the use, care or handling of animals or animal samples to complete training required by the Animal Welfare Act at the time of hire orientation. Training is tailored based on job duties and classification. Every IACUC protocol has an assigned veterinarian who has responsibility for assisting and advising the investigator. Individual investigators and staff are trained one-on-one by the veterinarian assigned to the research protocol.

Hands-on animal handling of NHPs is performed, almost exclusively, by Division of Veterinary Medicine personnel, which limits animal procedures performed by research personnel to small animals. One exception for NHP is the application of capsules containing ticks for *Borellia burgdorferi* studies. The capsules are placed using skin adhesive by research technicians who have been trained and have years of experience. Veterinarians observe the procedures to be sure research technicians are proficient. Small animal procedures (rodents and rabbits) are performed by investigators or their staff after individual training by veterinarians. Veterinarians observe these procedures until proficiency is assured. The training is documented.

Department of Comparative Medicine (Downtown and Uptown Campus)
Department of Comparative Medicine Staff (Veterinary and Animal Care Technicians)

All animal care technicians are trained in the following areas within the first six months of employment:

- Animal procurement: suppliers; institutional guidelines regarding ordering of animals; receiving animals; proper housing of animals; quarantine of newly arrived animals.
- Animal husbandry and care: laws, regulations, and policies pertaining to husbandry and care; environmental enrichment; environmental variables; caging; overcrowding; special caging; feeding, watering, experimental diets, and medications.
- Handling and restraint: proper handling techniques and methods for all species.
- Identification and record keeping.
- Animal health: physiologic parameters; health surveillance; signs of distress and disease; reporting of a death or illness.
- Safety and health considerations: naturally occurring and experimental; protective clothing and equipment; appropriate techniques for handling high-risk animals; importance of and procedure for reporting incidents.
- Euthanasia: legal and ethical considerations; appropriate and humane methods for each species; carcass disposal; emotional effects of euthanasia on personnel.

All new technicians attend a session of the DCM orientation training provided to research staff, described below. Continuing education is provided in the form of webinars, lectures, and refresher training sessions.

AALAS Certification
All animal care technicians are encouraged to become AALAS certified and an incentive program is in place for certification. Veterinarians and supervisors teach classes for ALAT, LAT, and/or LATG.

Research Staff
Protocol submission requires that all personnel working with animals submit (or have on file) their training appropriate to the specific protocol. Personnel added to protocols after approval are required to complete a personnel addition form (PAF) which documents their specific training regarding their role on the project. The DCM reviews all PAFs before granting access to animals. All researchers are required to attend an orientation training session provided by the DCM before access is granted to animals. This ongoing, monthly training includes a PowerPoint lecture, a handling wet lab, and a tour of the animal facility. The training program provides comprehensive general instruction on the handling, restraint, acclimation, transportation, analgesia, anesthesia, aseptic technique, record keeping, and euthanasia of all laboratory animal species housed within the animal facilities. The training program also includes an IACUC section that outlines origins and composition of the IACUC, reporting concerns, legislation such as the PHS Policy and AWA, emergency preparedness, and occupational health and safety. The IACUC section includes specific training on the use of

the Three R's to achieve the goal of humane experimental techniques, research or testing methods that minimize the number of animals required to obtain valid results and minimize distress, and how the institution assists with consideration of the Three R's prior to protocol approval. More intensive and specific instruction is provided whenever necessary or appropriate for the specific protocol. The DCM veterinary staff also provides guidance, instruction, and when necessary, services for all aspects of surgical procedures, including pre-, intra-, and post-operative care, especially in regard to minimizing pain, stress and distress. All training is logged into the lab animal management database.

IACUC Members

All new IACUC members undergo an initial training session (approximately 2 hours) with the chair or designee. The training presentation includes training on the Three R's, how to assess animal number justifications, research or testing methods that minimize the number of animals required to obtain valid results and minimize distress, and considerations for reviewing alternatives and literature search. Members are given access to the IACUC manual, which contains copies of all forms, IACUC administrative SOPs and policies, instructions and guidelines on how to conduct an inspection, examples of previous inspection notes and summaries, a presentation on "Meeting the Information Requirements of the Animal Welfare Act" from AWIC and articles on pertinent IACUC issues. Members are provided copies of relevant federal and state laws, regulations guidelines and institutional specific policies. Members are provided electronic access of the PHS Policy, OLAW/ARENA IACUC guidebook, the approved Animal Welfare Assurance, *Guide for the Care and Use of Laboratory Animals (Guide)* and the Animal Welfare Act. These materials are contained in an IACUC resource folder available to members at all times. All new members are required to complete the CITI training module IACUC Essentials. All non-affiliated members enroll in an online course for nonaffiliated members or complete the CITI training module for nonaffiliated members. Scientists and veterinarians are the primary reviewers for protocols. New members observe several meetings and then serve as a secondary reviewer with a more experienced reviewer prior to being assigned as a primary reviewer. Members are invited to attend IACUC focused conferences and are required to present a topic of interest from the conference at an IACUC meeting. Presentations are provided at meetings and these range from division or departmental presentations on animal care, behavior management, research specific, OLAW webinars or IACUC office developed presentations such as "Conducting an IACUC Inspection at Tulane." Articles of IACUC interest such as FAQ updates from OLAW are also presented on an interim basis. All presentations and articles are saved in a shared cloud based application so that members can access the materials at any time. All training is recorded in the lab animal management database

IV. Institutional Program Evaluation and Accreditation

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

(1) This Institution is Category 1 — accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The TNPRC and NOC are accredited by AAALAC as separate institutions.

V. Recordkeeping Requirements

A. This Institution will maintain for at least 3 years:
   1. A copy of this Assurance and any modifications made to it, as approved by the PHS
   2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations
   3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld
   4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Laura Levy, PhD
   5. Records of accrediting body determinations

B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional 3 years after completion of the activity.

C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

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

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: Laura Levy, PhD	
Title: Vice President for Research	
Name of Institution: Tulane University	
Address: 1440 Canal Street (b) (6) New Orleans, La 70112	
Phone: (b) (6)	Fax: (b) (6)
E-mail: llevy@tulane.edu	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature: (b) (6) Digitally signed by Laura Levy DN: cn=Laura Levy, o=Tulane University, ou=Office of Research, email=llevy@tulane.edu, c=US Date: 2018.03.28 12:33:45 -05'00'	Date: March 28, 2018

B. PHS Approving Official *(to be completed by OLAW)*	
Name/Title: Jane J. Na / Veterinary Medical Officer Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6705 Rockledge Drive RKL1, Suite 360, MSC 7982 Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817) Phone: +1 (301) 402-1922	
Signature: Jane J. Na -S Digitally signed by Jane J. Na -S DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, cn=Jane J. Na -S, 0.9.2342.19200300.100.1.1=2002213367 Date: 2018.03.28 15:43:44 -04'00'	Date: March 28, 2018
Assurance Number: **D16-00754 (A4499-01)**	
Effective Date: **March 28, 2018**	Expiration Date: **March 31, 2022**

VIII. Membership of the IACUC

IACUC Chairperson			
Name: Sheila Garrison			
Title: Chair, IACUC		Degree/Credentials: BS, CPIA	
IACUC Roster			
Name of Member/ Code*	Degree/ Credential	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
New Orleans Campus Roster			
[redacted] (b) (6)			Scientist
			Member
			Nonvoting Member
			Member
			Scientist
Gina Dobek Direct Program Authority	DVM, DACLAM	Director Department of Comparative Medicine (DCM)	Attending Veterinarian
[redacted] (b) (6)			Member
			Scientist
			Scientist (alternate to [redacted] (b) (6))
			Member (Alternate to [redacted] (b) (6))
			Non-Scientific Member
			Member (Alternate to [redacted] (b) (6))
			Scientist
			Non-Affiliated / Non-Scientific Member
			Non-Affiliated / Non-Scientific Member (Alternate to [redacted] (b) (6))
			Member
			Scientist (Alternate Chair)
			Scientist

TNPRC Roster			
[redacted] (b) (6)			Scientist
			Member
			Non-Affiliated / Non-Scientific Member
Rudolf P. Bohm Direct Program Authority	DVM, DACLAM	Chairman, Division of Veterinary Medicine,	Attending Veterinarian
[redacted] (b) (6)			Veterinarian
			Veterinarian
			Veterinarian (alternate to [redacted] (b) (6)
			Scientist
			Scientist (Alternate Chair)
			Nonvoting Member
			Scientist
			Scientist
			Veterinarian (alternate to [redacted] (b) (6)
			Scientist

* 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").

**** 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 be considered nonaffiliated.

[*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.*]

IX. Facility and Species Inventory

Date: October 16, 2017			
Name of Institution: Tulane National Primate Research Center			
Assurance Number: A4499-01			
North Campus-Research Colony			
Laboratory, Unit, or Building*	Gross Square Feet [*include service areas*]	Species Housed [*use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog*]	Approximate Average Daily Inventory
(b) (4)	9,110	Nonhuman primate (NHP)-rhesus, cynomolgus, African green, mangabey	158
	3,955	Mice Rats Rabbits	<1 <1 0
	4,080		None
	12,175	Nonhuman primate (NHP)-rhesus, cynomolgus, African green, mangabey	175
	1,180		None
	7,430	Nonhuman primate (NHP)-rhesus, cynomolgus, African green, mangabey Mice Rats Rabbits	100 13 <1 <1
	3,010		None
	14,380	Nonhuman primate (NHP)-rhesus, cynomolgus, African green, mangabey	127
	5,335	Nonhuman primate (NHP)-rhesus, cynomolgus, African	14

		green, mangabey	
(b) (4)	23,430	Nonhuman primate (NHP)-rhesus, cynomolgus, African green, mangabey	365
	4,263		None
	1800		None
South Campus-Breeding Colony			
(b) (4)	146,900	Nonhuman primate (NHP)-rhesus	394
	84,795	Nonhuman primate (NHP)-rhesus	102
	127,200	Nonhuman primate (NHP)-rhesus	504
	580,992	Nonhuman primate (NHP)-rhesus	2,038
	1,850	Nonhuman primate (NHP)-rhesus	49
	3,600	Nonhuman primate (NHP)-rhesus	70

Date: 10/10/17

Name of Institution: Department of Comparative Medicine (Downtown and Uptown Campus)

Assurance Number: A4499-01

Laboratory, Unit, or Building*	Gross Square Feet [*include service areas*]	Species Housed [*use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog*]	Approximate Average Daily Inventory
(b) (4)	20,900	Mouse	10,950
		Rat	78
	18,400	Mouse	3,050
		Rat	228
		Rabbit	42
		Frog	10
	8,000	Mouse	5,495
		Rat	270