Rhode Island Hospital
#A3922-01

Animal Welfare Assurance for Domestic Institutions

I, Peggy McGill as named Institutional Official for animal care and use at Rhode Island Hospital, 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: Rhode Island Hospital, The Miriam Hospital, Lifespan

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

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:

Peggy McGill, Vice President, Research Administration, serves as the Institutional Official. In this capacity, she appoints the Animal Welfare Committee (IACUC) and designates its chairperson(s). Ms. McGill has direct responsibility for implementation of the Policy, executive and administrative support of the IACUC and oversight of direct operation of the animal facilities. The IO delegates Animal Care Program responsibility to the Attending Veterinarian, Central Research Facility Director, and the IACUC. The Institutional Organizational Chart is included in Appendix 1. The Committee reports at least semi-annually and more frequently at its discretion, directly to the Institutional Official.

The Director, Central Research Facilities (CRF) operates the Hospitals' Central Animal Facilities under the general supervision of the Administrative Director of Animal Care. She is responsible for compliance with all of the requirements of the *Guide* as they apply to the care of animals in the facility and such satellites as are from time to time authorized by the IACUC.

Veterinary service, support and consultation are provided to the Central Animal Facilities by the Veterinary Staff at Brown University, the Hospitals' Medical School affiliate. A member of the veterinary staff is designated as Attending Veterinarian, as a member of the IACUC and is principal consultant to the IO on Veterinary Care Program matters.

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

1) Name: Tiffany M. Borjeson

Qualifications
- Degrees: D.V.M., DACLAM
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Dr. Borjeson received a Bachelor's of Science from the University of Massachusetts in Animal Science and her Doctor of Veterinary Medicine from the Virginia-Maryland Regional College of Veterinary Medicine in 2010. She completed a laboratory animal residency program and postdoctoral fellowship in Comparative Medicine at the Massachusetts Institute of Technology in 2013 and obtained Diplomate status in the American College of Laboratory Animal Medicine (ACLAM) in 2016. Prior to joining the Brown University veterinary staff as Associate Director in 2014, Dr. Borjeson managed two transgenic core facilities in the Boston area and served as the Clinical Laboratory Animal Veterinarian for Virginia State and Polytechnic Institute (Virginia Tech). Dr. Borjeson regularly attends AALAS, ACLAM, MSMR, NEBAALAS and AVMA continuing education conferences. She has attended specialty training courses including: Swine in Biomedical Research (surgery of swine) - MUSC 2014, Symposium of Social Housing of Animals - CDC 2017, Diagnostic Ultrasound - 2017.

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

2) Name: Jessica M. Johnston

Qualifications
- Degrees: D.V.M.
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Dr. Jessica M. Johnston graduated from the University of California, Davis School of Veterinary Medicine in 2013. She completed a residency in laboratory animal medicine from 2013-2016 at the University of Pennsylvania and is ACLAM board eligible.

Responsibilities: As a designee of the AV, Dr. Johnston oversees the health care of all animals in the RIH animal facilities including triaging clinical cases and performing diagnostics as needed, performing or supervising treatments, and providing support of surgical cases in the large animal operating room. As a voting member of the IACUC, she also assists investigators in protocol development, pre-reviews animal care and use protocols, reviews protocols and amendments, and advises the IACUC on animal care and use regulations, guidelines, and standards of veterinary care.

Time contributed to program: The veterinary time commitment to RIH is 100% percent of FTE with alternating weekend and holiday coverage. The veterinarians have an office at Rhode Island Hospital and at least one is onsite every Monday-Thursday, as well as being available at other times when needed. In case of emergencies outside of scheduled working hours, the veterinarians' home telephone and cell phone numbers are posted in the animal facility and with hospital security.

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. [*See section VIII*]

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 reviews are conducted using the NIH/OLAW sample semiannual program review checklist. Sections of the checklist are covered at normally-convened meetings of the full IACUC, such that the content of the entire checklist is covered twice each year, with completions by April and October. Key checklist topics include the Animal Care and Use Program, Disaster Planning and Emergency Preparedness, IACUC Protocol Review, Membership and Functions, Training, Records and Reporting Requirements, Veterinary Care (two sections), Personnel Qualifications and Training, Occupational Health and Safety of Personnel, Security, and Investigating and Reporting Animal Welfare Concerns.

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:

Inspections are conducted in April and October. Teams of two or more IACUC members conduct the inspections of the various facilities. The NIH/OLAW Sample Semiannual Facility Inspection Checklist and the "Guide" are used as references for this activity. All IACUC members are invited and encouraged to participate. Members of the IACUC inspect every area where animals are housed or used. The IACUC members are familiar with PHS policy and the "Guide," and are sufficiently knowledgeable that they can recognize deviations from PHS policy and the Guide. If a tour team is uncertain about potential compliance issues, notations are made on the tour report, which is reviewed by the Chairperson or Vice Chairperson and subsequently by the entire IACUC.

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:

   IACUC Staff compile the inspection reports from each of the individual inspection teams. The Chairperson or Vice Chairperson then composes a draft semi-annual report, which summarizes the inspection findings and other important issues. The semi-annual report includes a description of the nature and extent of the institution's adherence to the PHS Policy, the *Guide*, and the AWA, and a list of all Departures from the Guide, with justification for each departure. Deficiencies identified during the semi-annual review are classified as minor or significant, and a plan of corrective action and target completion dates developed by Administration and designated members of the committee is included. In most cases the date of correction is within days or weeks of discovery. Occasionally, where facilities issues are involved, targeted completion dates may have a longer horizon. In any case the IACUC monitors the progress of the corrective actions to assure that the institution is meeting its obligations.

   The draft report is forwarded to each of the IACUC members for comment. Once comments are received, the report is edited and a final version is presented at the subsequent IACUC meeting for member signature. Members are afforded an opportunity to express any dissenting or minority views, which are also included in the report. The report of the semi-annual review and facilities inspection, signed by all members of the IACUC, is sent to the Institutional Official.

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

   Individuals having concerns involving animal care and use at any of RIH's facilities are encouraged to contact any member of the RIH IACUC, the Institutional Official or the Administrative Director verbally or in writing. The Committee is charged by the institution with providing an official channel to receive, evaluate and respond to such concerns. IACUC contact information is provided to all researchers who work with animals during their initial orientation with Veterinary Services. Telephone numbers for veterinary and CRF management staff are posted within each animal facility. Contact information is also available on the IACUC webpage.

   Any concern brought to the Committee regarding the care and use of animals is promptly investigated by the Chairperson or Vice Chairperson. If the complaint has merit, the Chairperson or Vice Chairperson opens a formal investigation, which is handled by a subcommittee of the IACUC. The Chairperson or Vice Chairperson enlists the aid of any IACUC member(s) for the investigative subcommittee. An initial confidential interview between the reporting individual and subcommittee is preferred, however, the reporting individual may choose to remain anonymous. The ability to maintain anonymity is obviously important in any situation where the person fears possible reprisal.

   The IACUC subcommittee investigates any presented concerns in the same manner, regardless of the identity, status or the degree of subsequent participation by the reporting individual. No adverse action is taken against any party who reports, in good faith, any violation or apparent or threatened violation. The subcommittee members conduct interviews and gather information about the care and use of animals in question, until they feel reasonable conclusions can be drawn. They summarize their findings and generate a plan of recommended remediation. The subcommittee reports the reported concerns, evidence, conclusions and recommended remediation at the next regularly-scheduled IACUC meeting, at which time the IACUC reviews the subcommittee report and votes on whether to accept the findings and recommendations. Additional

information may be requested. Once accepted, reports of concerns, findings, and any corrective actions taken are conveyed in writing to the Institutional Official, OLAW, USDA and to the project Sponsor, as applicable.

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:

   Recommendations regarding any aspect of the institutions animal program, facilities, or personnel training are included in the semi-annual report to the Institutional Official. Recommendations or concerns may also be sent to the Institutional Official at any time between review cycles.

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:

   Veterinary consultation and pre-review is required before submitting a new or de novo application to the IACUC to allow for adequate in-person discussion and review of the IACUC application forms. Applications must be sent to the veterinarian at least two weeks before the IACUC deadline. IACUC submission deadlines are posted in the electronic protocol management system.

   New and de novo applications are submitted through the electronic protocol management system. The IACUC Staff (i.e. Manager and/or Coordinator) ensures that the applications are complete, assigns reviewers, and processes the application for full board review. The Staff prepare and share the submission documents with all members via the web-based protocol review system, including the agenda, applications to be reviewed, minutes from the previous meeting, and any other documents that will be discussed.

   Full committee review is required for all new and three year *de novo* applications. Full committee review of protocols requires a convened meeting of a quorum of the IACUC. At least seven days prior to the meeting, IACUC Staff provide each IACUC member, including alternate and non-voting members, access to all protocols being presented.

   The IACUC reviews all animal proposals regardless of the source of funding or whether they will be subjected to further review by funding sources. All projects are subject to a de novo review every three years. A complete new application is required at that time.

   A minimum of two members of the committee, one of whom is the Attending or Assistant Attending Veterinarian, are assigned to be the primary reviewers of the application. The other members of the committee also review the protocol as part of their responsibilities. The primary reviewers are charged with rendering an opinion regarding the appropriateness of approval. The primary reviewers review the completed Animal Care and Use Protocol (ACUP) along with supporting documentation, including the grant application for proposals seeking external funding. Supporting documentation for studies that will be internally funded may include a research plan that provides scientific justification for the study, identifies the specific aims of the study, and provides a detailed description of the proposed experiments that will involve animals, depending on their complexity. The Animal Care and Use Protocol (ACUP) and supporting documentation provide the scientific background and basis upon which the proposed hypothesis to be tested is evaluated.

If a primary reviewer or any other member of the committee needs additional information prior to rendering an opinion they can seek clarification from the investigator directly, or they may ask the Chairperson or Vice Chairperson of the committee, the Director of CRF, the Attending Veterinarian, or IACUC Staff to contact the investigator for additional information. In those instances, the investigator will be asked to bring additional clarifying information to the IACUC meeting where the protocol will be discussed and action taken.

The committee requires that the Department Chair/Chief review any application from a member of his or her department to ensure that its scientific merit and adequacy meet the standards of the department. The committee expects that all applications seeking external funding will be peer reviewed via any funding entity process. Nevertheless, the IACUC is responsible to assure that any use of animals is scientifically and ethically justified. If in its deliberations the committee finds that it does not possess the necessary expertise to make such judgments, it may seek experts from outside of the committee.

The Principal Investigator or his/her designee is encouraged to attend the IACUC meeting at which their protocol is discussed. All questions and concerns of the committee are conveyed to the investigator so that if additional clarification is required the investigator can provide it at that time. If any required information cannot be made available at the IACUC meeting, action on the proposal may be deferred to the next meeting. Once the committee and Principal Investigator (or his/her designee) have completed their discussions, the Principal Investigator (or his/her designee) leaves the meeting and the protocol is deliberated upon by the IACUC.

After deliberating, the convened IACUC votes to approve, require modification to secure approval, or withhold approval (defer). A protocol can only be approved by a majority of the committee members present at a duly convened meeting in which quorum has been established. Work covered by a protocol may not be initiated until a formal IACUC approval letter has been released. Committee members may not participate in either the review or approval for any protocol that they are involved with or have a Conflict of Interest (COI) with, except to provide information requested by the IACUC. Committee members adhere to RIH Conflict of Interest policies and excuse themselves from review, deliberation and voting as is consistent with those policies.

After the IACUC meeting, IACUC Staff sends out approval letters directly for protocols that are approved outright. For protocols that require modifications prior to approval, or for those that are deferred, relevant sections of the IACUC minutes, reviewer comments, and relevant sections of the minutes are prepared by IACUC Staff and forwarded to the investigator.

If the IACUC requires substantive revisions or clarifications it may defer the application to the next full board meeting, or vote to review the resubmitted application by Designated Member Review (DMR). The quorum of members present at a convened meeting may decide by unanimous vote to use designated member review subsequent to full committee review when modification is needed to secure approval. Any member may, at any time, request to see the revised protocol and/or request full board review of the revised protocol. The DMR process is codified in the IACUC Policy and Procedure Manual, section 3.5.2, which was unanimously approved by the entire IACUC at its regularly convened meeting in November of 2017. New members are informed of this process during New Member Orientation with the IACUC Chair and agree to the provisions and details of committee operations outlined in the IACUC Policy and Procedure Manual when they sign their appointment letter.

Designated reviewer(s) (DMR) may approve, require modifications to secure approval, or defer to the full committee for review. Designated reviewer(s) may not disapprove or withhold approval. If an application is assigned to more than one designated reviewer, the reviewers must be unanimous in any decision. They must all review identical versions of the application and, if modifications are requested by any one of the reviewers, the other reviewers must be aware of and agree to the modifications. The outcome of designated member review subsequent to full committee review is documented in the agenda and minutes for the next IACUC meeting.

At the discretion of the IACUC Chairperson or Vice Chairperson (in the Chairperson's absence), a special priority meeting of the full committee may be convened for consideration of a new protocol or a significant change in an existing protocol when waiting until the next regularly scheduled meeting will result in a detrimental interruption of the project, loss of funding, or prevent it from being considered for funding. As with normally-reviewed protocols, approval of protocols reviewed at specially convened meetings will be granted only where quorum is met and a majority vote is recorded.

Exception to the requirement for full board review: Reciprocal Administrative Review
Occasionally, a researcher will receive a grant for work that will be done at another institution, or will be sub-contracted to a colleague at another institution. If no animal work will be conducted at Rhode Island Hospital, then the IACUC at the institution where the work will be performed will be considered as the IACUC of record. Once IACUC approval has been granted at the performance site, the Rhode Island Hospital IACUC will use designated member review (DMR) of the proposal. Two members of the IACUC review each protocol submitted for reciprocal administrative review. The reviewers are assigned by the Committee Staff using a rotating list of reviewers approved by the Chair and based upon identified expertise. In each case the reviewing team includes at least one veterinarian. Prior to DMR, all IACUC members are notified via email that the application has been received and assigned to designated review, affording them the opportunity to call for full committee review (FCR). If any member request FCR, the application will be placed on the agenda for review at the next convened meeting, using the FCR process described above. The designated reviewers have access to the approved protocol and the approval letter from the performance site, and may request a copy of any supporting material. As noted above, designated reviewer(s) (DMR) may approve, require modifications to secure approval, or defer to the full committee for review. Designated reviewer(s) may not disapprove or withhold approval. If an application is assigned to more than one designated reviewer, the reviewers must be unanimous in any decision. They must all review identical versions of the application and, if modifications are requested by any one of the reviewers, the other reviewers must be aware of and agree to the modifications. The outcome of designated member review subsequent to full committee review is documented in the agenda and minutes for the next IACUC meeting.

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

The Rhode Island Hospital IACUC recognizes three types of protocol changes: 1) Significant Changes, which are those that have the potential to impact substantially and directly on the health and well-being of experimental animals; 2) Non-Significant Changes, which are those that alter the way animals are used or handled, but do not substantially or directly impact

health and well-being, and 3) Minor Administrative Changes. The review process for each of the three differs slightly.

Significant Changes
Proposed Significant Changes to approved Animal Care and Use Protocols (ACUPs) are reviewed and approved via the designated review process as described in Part III. D.6.above. Significant changes are reviewed by at least two members of the IACUC, one of whom must be a veterinarian. Reviewers are assigned by IACUC Staff using a rotating list of reviewers approved by the Chair and based upon identified expertise.. All IACUC members are notified (via email and agenda) of the proposed request for changes and any member may request a full board review. A three (3) business day wait period is required before approval of Significant Changes. Members who have not responded within the notification period are considered to have agreed in silence to allowing the DMR review to proceed.

Changes are considered to be significant when they fall into the following categories:
- An increase in animal numbers. For rats and mice, an increase in animal numbers greater than 10%.
- Addition of a new animal species.
- Addition of a survival surgical procedure where none was originally included.
- Addition of a major survival surgical procedure.
- Scheduling of access or restriction of food and/or water, other than routine restriction of food prior to surgery.
- Any increase in pain category (e.g. from C to D, C to E, or D to E).
- The introduction of prolonged restraint.
- Change of Principal Investigator
- Changes in housing and or use of animals in a location that is not part of the program overseen by the IACUC.
- Changes that impact personnel safety

Non-Significant Changes
Proposed Non-Significant Changes to approved Animal Care and Use Protocols (ACUPs) are reviewed and approved via the designated review process as described in Part III. D.6.above. Non-Significant changes are reviewed by at least two members of the IACUC, one of whom must be a veterinarian. Reviewers are assigned by IACUC Staff using the rotating list of reviewers approved by the Chair and based upon identified expertise. All IACUC members are notified (via email and agenda) of the proposed request for changes and any member may request a full board review. A one (1) business day wait period is required before approval of Non-Significant Changes. Members who have not responded within the notification period are considered to have tacitly agreed to allow the DMR review to proceed.

Changes are considered to be Non-Significant when they alter the way animals are used or handled, but do not meet the definition of significant changes as described above.

Minor Administrative Changes
Minor Administrative changes to approved Animal Care and Use Protocols (ACUPs) are reviewed and approved by the IACUC Staff. All IACUC members are notified (via the distributed IACUC agenda) that IACUC Staff have processed the proposed request for changes. No wait period is required for Minor Administrative Changes.

The following types of changes are considered to be Minor Administrative changes because they do not substantively alter the protocol or the care and use of animals:

- Addition of personnel
- Change in commercial vendor
- Relocation of performance site (e.g. lab move or use of a different animal facility building/room)
- Correct errors in the Animal Care and Use Protocol (ACUP) (e.g. minor mistakes in description of dosage/route that are discovered after initial review, as agreed upon by the veterinarian)
- Addition or change of a financial responsibility cost center

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 IACUC Staff notifies investigators via the electronic protocol management system regarding the outcome of the IACUC's review. The IACUC's decision is sent with the applicable sections of the IACUC minutes, as well as any reviewer comments discussed at the meeting. The minutes and comments provide the conditions for IACUC approval, or reasons for deferral, or modifications required to secure IACUC approval. Investigators must respond to the IACUC review with, at minimum, a revised protocol that is then re-reviewed following the procedures outlined in part III.D.6, above. If approval of an activity is withheld, the notification letter includes a statement of the reason for its decision, as well as an invitation for the investigator to respond in writing or in person. The IACUC notifies the institution of its decisions by conveying the text of each meeting's minutes to the Institutional Official, which include the IACUC deliberations on each new and de novo protocol as well as a summary of all other IACUC activities for the month.

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:

In years one and two, continuing review is conducted by designated member review (DMR) of brief progress reports, using the process described in Part III.D.6, above. Continuing reviews are completed prior to each protocol's one- and two-year anniversaries. The electronic protocol management system sends reminders to investigators 90, 60, and 30 days prior to expiration, to provide ample time for preparation and review of the progress report. The progress report queries the investigator as to whether the project continues to be necessary and scientifically justified. It also requires assurance from the investigator that no new alternatives to the use of animals or the use of potentially painful procedures have become available. A minimum of two reviewers conduct the review, one of whom is a veterinarian. Reviewers are assigned by IACUC Staff using the rotating list of reviewers approved by the Chair and based upon identified expertise. A list of all continuing reviews is sent to all IACUC members via email to afford them the opportunity to participate.

De novo continuing reviews are completed prior to each protocol's three-year anniversary, following the procedures outlined in part III.D.6, above. Researchers are notified 90 days

before the third-year anniversary date to afford ample time for preparation and submission of the de novo application. The ACUP and supporting documentation provide the scientific background and basis upon which the proposed hypothesis to be tested is evaluated. A minimum of two members of the committee, one of whom is the Attending or Assistant Attending Veterinarian, are assigned to be the primary reviewers of the application. The other members of the committee also review the protocol as part of their responsibilities. The two primary reviewers are charged with rendering an opinion regarding the appropriateness of approval. The primary reviewers review the completed Animal Care and Use Protocol (ACUP) along with supporting documentation, including the grant application for proposals seeking external funding. Supporting documentation for studies that will be internally funded may include a research plan that provides scientific justification for the study, identifies the specific aims of the study, and provides a detailed description of the proposed experiments that will involve animals, depending on their complexity. The Animal Care and Use Protocol (ACUP) and supporting documentation provide the scientific background and basis upon which the proposed hypothesis to be tested is evaluated.

Continuing oversight is achieved via animal care staff observations and daily reporting of veterinary staff rounds to the veterinarian. Progress and problems are conveyed to the IACUC via formal reporting of unanticipated problems, monthly veterinary reports to the IACUC, monthly facilities reports from the Central Research Facility Director, annual progress reports, triennial de novo IACUC application submission, and post-approval monitoring (for selected projects).

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 procedures for suspension and ongoing activity are detailed in the IACUC Policy and Procedure Manual, Section 8 Animal Welfare Concerns, Unanticipated Problems, and Non-Compliance Situations. In cases involving misuse or unauthorized use of animals, the IACUC Chair (or Vice Chair in the Chair's absence) is empowered to temporarily halt any animal activity. In those instances the IACUC Chair (or Vice Chair) will promptly notify the full committee and the Institutional Official. All other cases will be brought to the attention of the IACUC at the next normally convened meeting.

The IACUC is empowered to suspend a project if it finds violations of Lifespan policy, PHS Policy, the *Guide*, the Institution's Assurance, or the Animal Welfare Regulations. The IACUC may suspend an activity only after review of the matter at a convened meeting. Suspension requires a majority vote by a quorum of the members. Upon suspension of an activity, the Principal Investigator is informed, in writing, of the details of the suspension and the requirements for re-review. The Institutional Official is notified any time the IACUC votes to suspend an ongoing research activity. The Institutional Official, in consultation with the IACUC, will review the reasons for suspension, take appropriate corrective action, and report the action with a full explanation to OLAW. The Institutional Official also reports suspensions to USDA and any applicable funding agencies, as appropriate. The IACUC may vote to lift the suspension only after review of the matter at a convened meeting of a quorum of the IACUC, and with the vote of a majority of the quorum present.

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 Personnel Occupational Health Program (POHP) is coordinated and monitored by Employee & Occupational Health Services (EOHS) staff. The program covers all members of the animal care staff and all research laboratory personnel who do or may work with animals, including students and volunteers. The program includes an interview/examination at EOHS at the time of employment (or of joining a lab for students and volunteers), followed by annual health surveillance monitoring through the use of confidential questionnaires.

Newly hired personnel are interviewed by the EOHS nurses, medical histories are established and physical examinations may be performed. As part of the process, an animal-directed health surveillance questionnaire is completed and reviewed by EOHS personnel. Positive responses are evaluated by EOHS personnel who develop a plan for prevention and/or clinical management. Current tetanus prophylaxis is required for all research personnel, including animal care staff, students and volunteers. EOHS maintains tetanus prophylaxis records. Monitoring of ongoing risk is via yearly submission of a health surveillance questionnaire. As with the intake questionnaire, the annual health surveillance questionnaire is evaluated by EOHS personnel who follow-up positive responses with a plan for prevention and/or clinical management. Yearly tuberculosis testing is offered for all RIH personnel.

The Personnel Occupational Health Program is extended to members of the institutional staff who may occasionally work in laboratory animal facilities, but who don't necessarily have frequent contact with animals, such as maintenance and housekeeping personnel. Workers with limited exposure are identified by management who refer them to EOHS, which then addresses any potential health risks. The questionnaire includes information concerning allergies and pregnancy, and recommends consultation with EOHS personnel or the employee's primary care physician with any additional work-related health concerns.

In addition to the personal health risk analysis, occupational health and safety training is provided during a mandatory orientation session for laboratory and animal care personnel. At the mandatory orientation session, information about zoonoses, personal hygiene, animal related allergies and occupational health and safety is covered by Veterinary Services, as is information regarding animal bites and scratches, how to address injury, and who to contact for reporting purposes (i.e. supervisor, EOHS, Personal Care Physician, or Emergency, where applicable). This information is posted in the animal facilities and also repeated in the mandatory annual training. Students and volunteers who have or may have animal contact receive the same training as laboratory and animal care personnel. The Veterinarian discusses relevant zoonotic considerations with Principal Investigators at the time of protocol submission, and a section on zoonoses is included in the manual of animal care policy and procedures (CRF manual). Specific human health related information for each animal species housed at RIH as well as information about pregnancy, illness, and immunodeficiency are included in the Personnel Occupational Health Program description, within the Central Research Facilities Manual. During orientation, personnel are directed to the manual which is available on the website. Additionally, the annual health surveillance questionnaire reminds personnel to consult with EOHS in the event of pregnancy or a change in health status.

All new employees are informed of OSHA's Hazard Communication Standard (Right-to-Know) during their orientation to the hospital. This orientation is conducted during the hospital's general orientation program for new employees and consists of an overview of the Standard presented

via a videotape. Department managers or the employee's supervisor are responsible for expanding upon the hazardous materials information provided to employees during orientation. Managers are to provide specific training for employees on:

- Hazardous agents used in their departments
- OSHA's Hazard Communication Standard
- Interpreting Material Safety Data Sheets applicable to their work area
- How to interpret cautionary information on container labels
- How to protect themselves when using hazardous materials
- How to deal with a hazardous materials spill, accident, or other emergency
- Applicable hospital and departmental policies and procedures concerning hazardous materials, including proper disposal of hazardous waste

Managers whose employees are involved with hazardous materials keep records of all employees who receive training or retraining involving hazardous substances.

All protocols involving the use of hazardous biological or chemical agents or radiation are reviewed by the Institutional Biosafety Committee or the Radiation Safety Committees, respectively. Procedures for protecting personnel from hazardous agents are stipulated by the respective safety committee; all reviews and safety plans must be completed prior to IACUC approval. Principal Investigators licensed by the Radiation Safety Committee are responsible for implementing appropriate safeguards when radioisotopes are used in animal work. Recommended area and personnel health monitoring may be done by the Radiation Safety Office, EOHS or by other specialized departments. All exposures and possible exposures to hazardous agents in the animal facilities are reported to CRF management, and personnel are then sent to the EOHS for evaluation and any necessary treatment or referral.

The educational background and experience of a given employee are taken into consideration when developing occupational safety-related training plans. BSL-2/ABSL-2 training is conducted annually by the PI, lab manager or employee's supervisor, and supplemental training takes place if new hazardous substances enter the work area. Employees are to be familiar with important concepts, understand them, and demonstrate that they know how to safely handle and use workplace chemicals before using them.

All personnel are trained to maintain high standards of personal hygiene and appropriate facilities are provided. Personal protective clothing and equipment is provided. In the event of illness or injury, personnel are referred to EOHS during normal business hours, and to the hospital's emergency department at all other times. All accidents, scratches, bites, and allergic reactions are required to be reported and an accident report submitted to EOHS. Currently, the institution does not house non-human primates.

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

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

Training is mandated for everyone responsible for animal protocols or who have contact with live animals; including scientists, laboratory staff, animal technicians, and IACUC members.

Training covers the Federal, State, and institutional regulations and/or policies that govern research animal use, the requirement to minimize the number of animals necessary to obtain valid results and to limit animal pain and distress, proper veterinary care and monitoring, and requirements for husbandry, biological and chemical hazards use, personnel occupational health and safety, personnel training with species and techniques. The list below describes in further detail the kind of training required for each category of personnel involved in the animal program:

1) All Personnel (Principal Investigators, Research Staff, Animal Care Staff, and IACUC Members): All personnel who submit Animal Care and Use Protocols or work with laboratory animals in Lifespan facilities are required to attend a one-on-one orientation meeting with the Supervisor of the Central Research Facilities (CRF) or a Veterinary Services Coordinator. The meeting includes a general overview of the animal care program and facilities at Lifespan, as well as a brief overview of the federal regulatory and accreditation agencies. Instruction is also provided on the requirement and methods for reporting deficiencies in animal care and treatment, and links are provided to the Central Research Facilities (CRF) website where the CRF Policy and Procedure Manual is available for review and download.

2) Research Staff (Principal Investigators, Research Staff, and Research Techs): All research staff involved in animal research must complete a mandatory training course designed to provide an overview of the regulatory and ethical backdrop for the use of animals in research, as well as familiarity with the basics of the IACUC review and approval process, reporting mistreatment or noncompliance, occupational safety, and animal care. The training course is administered through the CITI Program online format and each participant must obtain a passing score on an online quiz to be considered trained. Additional training modules and quizzes are required for individuals using rodents and large animals. Additional institution-specific rodent and large animal training is required annually.

Principal Investigators who are new to the Institution are required to meet with the Chairperson or Vice Chairperson of the IACUC. The Chair(s) reviews the mission of the committee, how it functions, and how strives to work with the investigator to assure that all research conducted at the Institution meets the highest ethical and scientific standards. The Chair(s) describes the ethical and legal framework that guides IACUC decision making to assure that the investigators are prepared to undertake their work cognizant of all applicable regulations.

Competency must be demonstrated before anyone is allowed to perform procedures on animals independently (e.g. injections, euthanasia, surgery, etc.). Procedural training may be provided by veterinary services, animal care or research staff with expertise in the procedure in question. Competency is documented on the Laboratory Animal Privileges and Procedures Documentation Form via signature by the supervising trainer. Principal Investigators maintain training records for their staff. All personnel who perform rodent survival surgeries are also required to complete the rodent surgery module of the AALAS learning library, which provides information on the basic principles of rodent surgery and reflects the IACUC Policy for conducting rodent survival surgery.

3) Central Research Facilities Staff (supervisors, coordinators, and technicians): All central research facilities staff (except technicians) must also complete the mandatory training course designed to provide an overview of the regulatory and ethical backdrop for the use of animals in research, as well as familiarity with the basics of the IACUC review and approval process,

reporting mistreatment or noncompliance, occupational safety, and animal care. The training course is administered through the CITI Program online format and each participant must obtain a passing score on an online quiz to be considered trained. All central research facilities staff (including technicians) must take the CITI Program institution-specific online rodent and large animal training annually.

Staff meetings are held for the Central Research Facilities (CRF) employees monthly. Animal care policies are reviewed at staff meetings, as are any projects involving hazardous materials or substances. Presentations are also made by investigators with ongoing animal research programs, providing in depth understanding of the rationale and goals of animal research. Lifespan subscribes to the AALAS learning library, and all CRF staff members are encouraged to review the available modules. The institution encourages for activities leading to certification and provides support for the attendance at regional and/or national meetings, with one or two staff members attending every year.

4) IACUC Members: New members are required to complete the CITI Program training module "Essentials for IACUC Members, Basic Course". Copies of the PHS Policy on Humane Care and Use of Laboratory Animals, the Animal Welfare Act, the Animal Welfare Regulations, Institutional Animal Care and Use Guidebook (OLAW, NIH), the Guide for the Care and Use of Laboratory Animals, the Institution's OLAW Assurance, the Institution's IACUC Policy and Procedure Manual, and the Institution's CRF Policies and Procedure Manual are available on-line or provided in paper or electronic format (via the Institution's IACUC webpage).
New members attend IACUC meetings immediately and have full access to the items under review, but may not function as a primary reviewer for several meetings until they feel comfortable with the process. Training for the semi-annual facilities inspection is accomplished through informal mentoring from more senior members of the IACUC. Facilities inspections are conducted in teams of two or three members with new members paired with more experienced members.

Ongoing training is accomplished via the distribution of pertinent literature, protocol-related discussion of applicable sections of the Guide, PHS Policy and USDA Regulations, participation in OLAW's quarterly webinars, and periodic presentations by in-house staff. Funding is available for member attendance at training workshops, such as those provided by the Massachusetts Society for Medical Research (MSMR) and Public Responsibility in Medicine and Research (PRIM&R).

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.

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, Peggy McGill, MA, CRA.
   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, Peggy McGill, Vice President, Research Administration.
   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: Peggy McGill, MA, CRA	
Title: Vice President, Research Administration	
Name of Institution: Rhode Island hospital	
Address: *(street, city, state, country, postal code)* 1 Hoppin St Coro West, Suite 1.300 Providence RI 02903	
Phone: (401)-444-8697	Fax: (401)-444-7960
E-mail: pmcgill@lifespan.org	
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: Peggy McGill	Date: 4/2/18

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 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: 2018.04.10 13:13:36 -04'00'	
Signature:	Date: April 10, 2018
Assurance Number: **D16-00532 (A3922-01)**	
Effective Date: **April 10, 2018**	Expiration Date: **April 30, 2022**

VIII. Membership of the IACUC

Date:03/28/18	
Name of Institution: Rhode Island Hospital	
Assurance Number: A3922-01	

IACUC Chairperson

Name*:Douglas C. Moore	
Title*: Research Scientist, Department of Orthopedics	Degree/Credentials*:M.S.
Address*: *(street, city, state, zip code)* Rhode Island Hospital Coro West 5th Floor 1 Hoppin St. Providence, RI 02903	
E-mail*: douglas_moore@brown.edu	
Phone*:(401)-444-8904	Fax*:(401)-444-4418

IACUC Roster

Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
2, Vice Chair	PhD	Dept. of Pediatrics	Scientist
3	BS, LATG, CPIA	Director Central Research Facilities	Scientist
5	PhD	Division of Surgical Research	Scientist
10	DVM	Director of Veterinary Services (local zoo)	Scientist, Non-Affiliated
18	MBA, LAT	Research Operations Compliance, Central Research Facilities	Alternate for member #3
20	MD	Division of Hematology/Oncology	Scientist
21	MD, PhD	Division of Cardiothoracic Surgery	Scientist
22, Tiffany Borjeson	DVM, DACLAM	Associate Director of Animal Care, Brown University	Attending Veterinarian
23	PhD	Department of Pediatrics	Scientist
25, Jessica Johnston	DVM	Staff Veterinarian, Brown University	Veterinarian
26	MS	Medical Simulation Center Manager	Nonscientist
27	PhD	Department of Pathology	Scientist
8	DVM, DACLAM	Director of Animal Care, Brown University	Alternate for Dr. Johnston

* 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. Other Key Contacts (optional)

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

Contact #1	
Name: Jacqueline Poore	
Title: Research Compliance Program Manager	
Phone: 401-444-5843	E-mail: jpoore@lifespan.org
Contact #2	
Name: Kate Brilliant	
Title: Research Review Compliance Coordinator	
Phone: 401-444-2093	E-mail: kbrilliant@lifespan.org

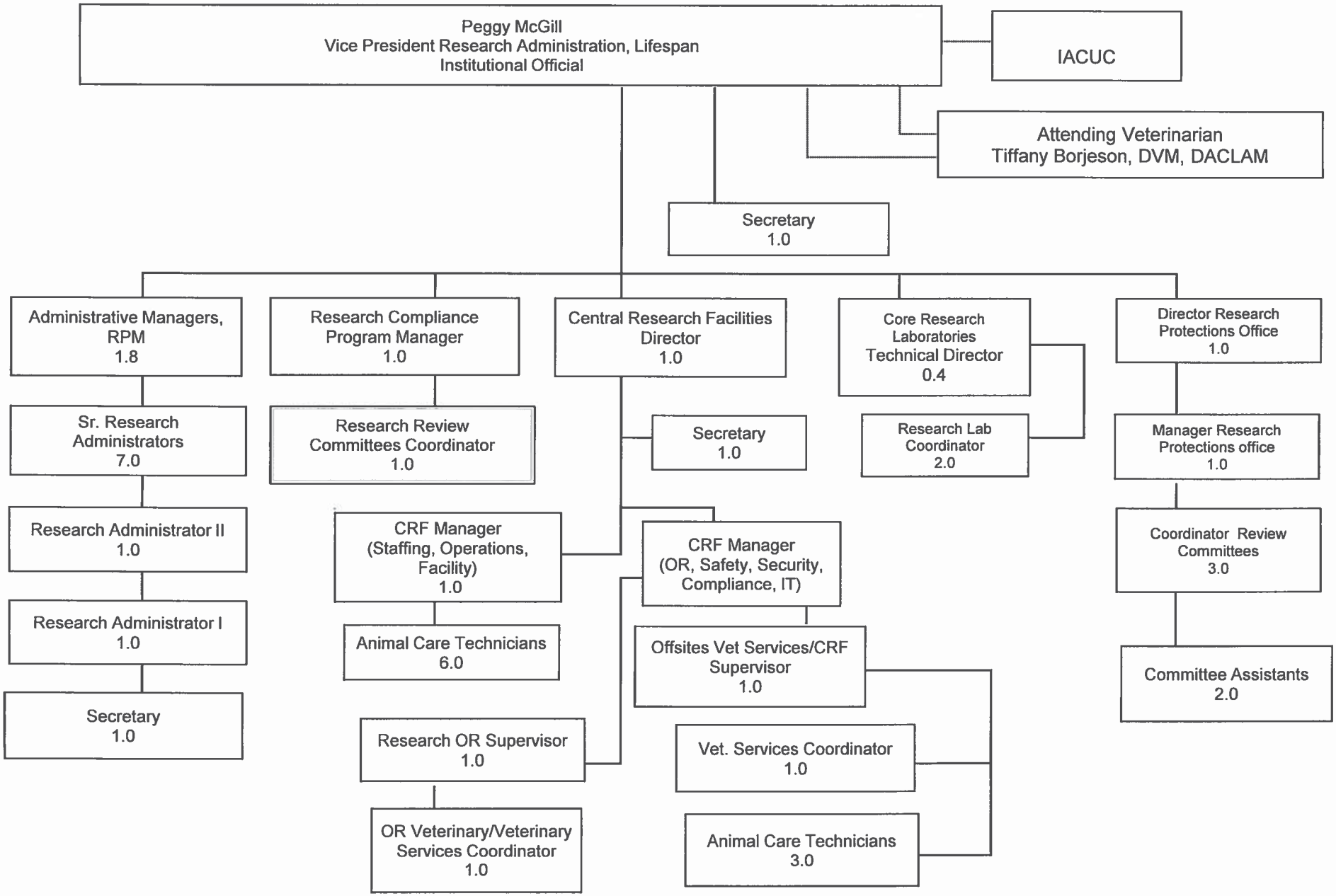
X. Facility and Species Inventory

Date:12/15/17			
Name of Institution: Rhode Island Hospital			
Assurance Number: A3922-01			
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
Main Facility	14.732	Mouse Rat Rabbit Swine	800 100 52 9
Satellite 1 (CW)	5,100	Mouse Rat Rabbit	1220 80 16
Satellite 2 (CE-Barrier)	6,405	Mouse Rat	1800 30
Satellite 3 (CI)	3,346	Mouse Rat	240 16

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

RESEARCH ADMINISTRATION (LIFESPAN)

ORGANIZATIONAL CHART



ORA chart Rev 03/2018