

**BROOKHAVEN NATIONAL LABORATORY**  
**BROOKHAVEN SCIENCE ASSOCIATES, LLC.**  
Assurance D16-00067 (Legacy A3106-01)

**Animal Welfare Assurance for Domestic Institutions**

I, Robert Tribble as named Institutional Official for animal care and use at Brookhaven National Laboratory, 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, DHHS, NSF and/or NASA, (if applicable). This Assurance covers only those facilities and components listed below.

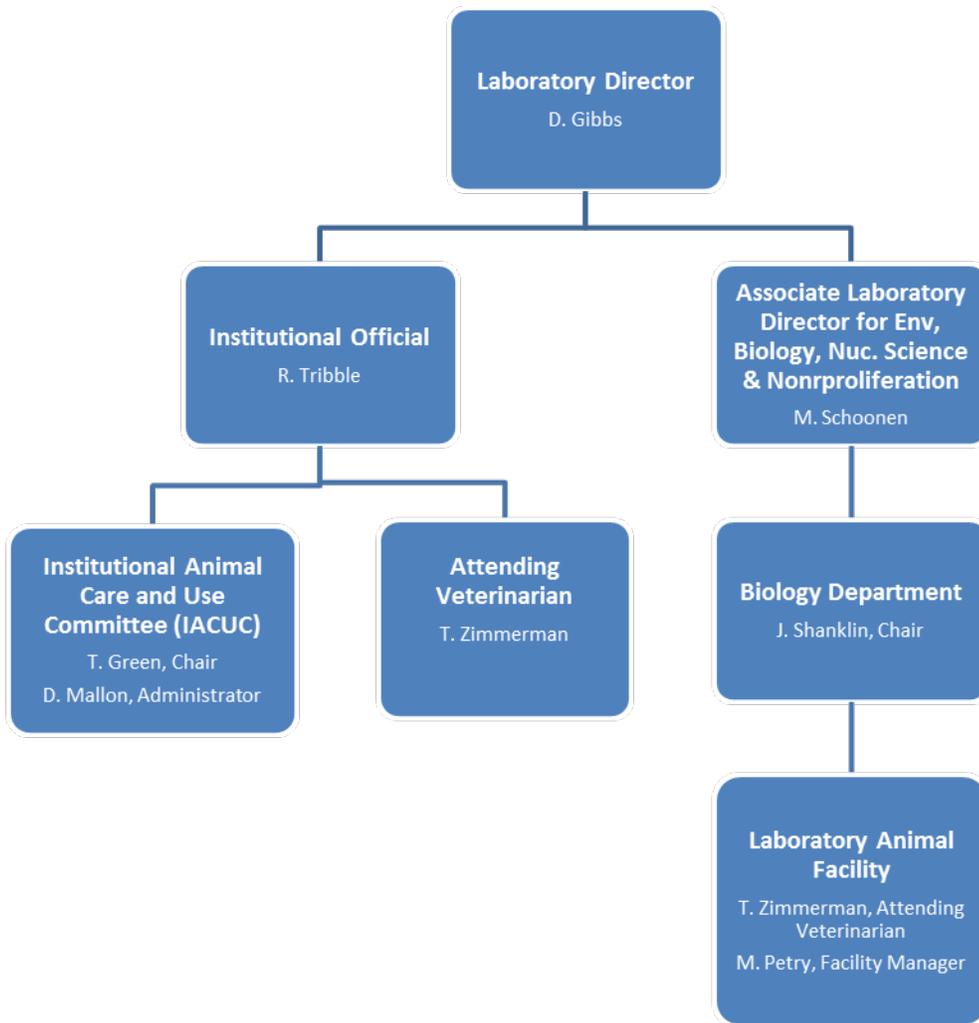
- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:  
There are no satellite facilities or other components covered by this Assurance.
- B. The following are other institution(s), or branches and components of another institution:  
There are no other institutions.

**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:



Note: As indicated above, there are direct and open lines of communication between the IACUC and the Institutional Official (IO) and between the Veterinarian and the IO

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

1. Name: Thomas A. Zimmerman, D.V.M., M.P.V.M., A.C.L.A.M.

Qualifications:

- Degrees: D.V.M., UC-Davis, 1987; M.P.V.M; Diplomate A.C.L.A.M., 1992.
- Training and/or experience in laboratory animal medicine: Director, Veterinary Services, SUNY-Stony Brook, 2001 – Present.

Authority: Dr. Zimmerman has delegated program authority and responsibility for the Institution's animal care and use program. He has unfettered access to all research animals at BNL.

Time Contributed to Program: Dr. Zimmerman is present at the Institution an average of approximately 16 hours per month. One-hundred percent of this time is contributed to the animal care and use program. In addition, Dr. Zimmerman contributes on average approximately eight hours per month to the program while off-site reviewing protocols and providing consultation on various program related topics

2. Name: Rachel Brownlee, L.A.T.G., D.V.M.

Qualifications:

- Degrees:  
B.S. Veterinary Science, College of Agriculture and Life Sciences, University of Arizona 12/07  
Laboratory Animal Technologist Certification, American Association for Laboratory Animal Science 01/13  
D.V.M., School of Veterinary Medicine, University of California–Davis 05/16  
Licensed in CA
- Training and/or experience in laboratory animal medicine: Dr. Brownlee has acquired experience with many species of animals during her years in the field of laboratory animal medicine.

Responsibilities: In Dr. Zimmerman's absence, Dr. Brownlee has delegated program authority and responsibility to implement the PHS Policy and the recommendations of the Guide.

Time Contributed to Program: Backup Veterinarian as needed

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

D. The IACUC will:

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

- The IACUC will meet at least once every six months to review the Institutional Program for Humane Care and Use of Animals.
- The Committee uses the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review.
- The Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist to facilitate the evaluation.
- The evaluation will include, but not necessarily be limited to, a review of the following:
  - a) IACUC Membership and Functions;
  - b) IACUC Records and Reporting Requirements;
  - c) Husbandry and Veterinary Care (all aspects);
  - d) Personnel Qualifications (Experience and Training);
  - d) Occupational Health and Safety;
  - f) The Disaster Plan
- The evaluation may include a review of the Institution's PHS Assurance.
- Program deficiencies noted during the review will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency.

- IACUC-approved departures from the PHS Policy and the Guide including reason for each departure are also included. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.
  - Subcommittees may be used to conduct all or part of the reviews. However, no member will be involuntarily excluded from participating in any portion of the reviews.
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:
- At least once every six months, at least two members of the IACUC will visit all facilities where animals are housed and surgical areas. Other areas may include holding areas, animal care support areas, storage areas, procedure areas, and laboratories where animal manipulations are conducted. Vehicles and other equipment used for transporting animals are also inspected.
  - The Committee uses the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review.
  - The Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist to facilitate the evaluation.
  - Deficiencies noted during the inspection will be categorized as significant or minor. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel. The Committee will develop a reasonable and specific plan and schedule for correcting each deficiency
  - Subcommittees may be used to conduct all or part of the inspections. However, no member will be involuntarily excluded from participating in any portion of the inspections.
  - For individual facilities that house or involve only non-USDA covered species, the Institutional Animal Care and Use Committee (IACUC) may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities. The IACUC may invite ad hoc consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and 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:
- Individual IACUC members will convey their observations to the IACUC Administrator, who will draft the reports using the sample OLAW Semiannual Report to the Institutional Official format from the OLAW website.
  - The reports will contain a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy.
  - The reports will identify specifically any IACUC approved departures from the provisions of the Guide and the PHS Policy, and state the reasons for each departure. If there are no departures the reports will so state. Approved departures must be approved as part of a protocol, protocol amendment, or other written document, using either FCR or DMR as delineated below in Section III.D.6.
  - Departures from the provisions of the Guide that are not IACUC approved are considered deficiencies and addressed as such, i.e., the IACUC will develop a reasonable plan and schedule for discontinuing the departure or for having the departure properly reviewed and approved.

- The reports will distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule for correcting each deficiency.
  - If some or all of the institution's facilities are accredited by AAALAC International the report will identify those facilities as such.
  - Copies of the draft reports will be reviewed, revised as appropriate, and approved by the Committee.
  - The final reports will be signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will so state.
  - Following completion of each evaluation, the completed report will be submitted to the Institutional Official in a timely manner.
  - The IACUC Administrator tracks noted deficiencies to ensure they are appropriately resolved. Any issues that cannot be resolved are forwarded to the IACUC Chair for final resolution.
4. Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:
- Any individual may report concerns to the IO, IACUC Chair, IACUC Administrator, Attending Veterinarian or any IACUC member. Concerns may be reported anonymously.
  - Notices are located in the animal facilities advising individuals how and where to report animal welfare concerns and stating that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals.
  - All reported concerns will be brought to the attention of the full Committee.
  - If necessary, the IACUC Chair will convene a meeting to discuss, investigate, and address any reported concern.
  - Reported concerns and all associated IACUC actions will be recorded in the IACUC meeting minutes.
  - The Committee will report such actions, in writing, to the IO and, as warranted, to OLAW. Reports to the IO may be either via meeting minutes, semiannual report of IACUC evaluations, or separate letter. Reports to OLAW will be in writing and through the IO. Initial reports to both the IO and OLAW may be made verbally.
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 aspects of the institution's animal program, facilities or personnel training are discussed and developed by the Committee.
  - The Committee's recommendations are included in the IACUC Meeting minutes or a report of the IACUC's evaluations or a separate letter.
  - The documents are reviewed and approved by the Committee and then submitted to the IO.

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:
- Protocols are submitted to the IACUC Administrator.
  - A pre-review is performed by the IACUC Administrator to ensure the submission is complete and appropriate for IACUC review and by the Attending Veterinarian to ensure proper animal husbandry and pain/distress procedures are being proposed.
  - The IACUC is sent a copy of the protocol one and one-half weeks before the meeting as part of the Agenda.
  - No member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.
  - The IACUC may invite consultants to assist in reviewing complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.
  - In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC will conduct a review of those components related to the care and use of animals and determine that the proposed protocols are in accordance with the PHS Policy. In making this determination, the IACUC will confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the protocol is consistent with the Guide unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms to the institution's PHS Assurance and meets the following requirements:
    - a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
    - b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
    - c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.
    - d. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
    - e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
    - f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
    - g. Methods of euthanasia used will be consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

- Prior to the review, each IACUC member will be provided with a written descriptions of activities (protocols) that involve the care and use of animals and any member of the IACUC may obtain, upon request, full committee review of those protocols.
- Generally, Full Committee Review (FCR) will be used. However, should a situation warrant it, the institution or IACUC may want to use the designated-member review (DMR) or Veterinary Verification and Consultation (VVC) method.
- If FCR is requested, approval of those protocols may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.
- FCR meetings are held in person. Emergency FCR meetings may be held by teleconference.
- Any use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24<sup>th</sup>, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.
- A quorum is required for all convened meetings and shall consist of a majority of the voting members of the Committee.
- The voting Committee members comprising any quorum shall not have a conflict of interest with respect to the matter being decided. Conflicted members may participate in the discussion of the matter but may not vote on the matter nor contribute to the quorum. A member may abstain from voting on a protocol. The abstention will be included in the minutes of the meeting.

Following discussion, the IACUC decision and any modifications required are reiterated. The IACUC Chair then calls for a show of hands and the votes are recorded in the minutes.

- The IACUC decision will be one of the following:
  - a. Approval
  - b. Modifications Required to Secure Approval
  - c. Approval Withheld
- **Required Modifications Subsequent to FCR:** When the IACUC requires modifications to secure approval, such modifications are reviewed as follows:
  - a. By FCR or DMR following all applicable procedures as delineated in the PHS policy and 9CFR.
 

**or**
  - b. If all members of the IACUC are present at a meeting, the committee may vote to require modifications to secure approval and then by unanimous consent agree to have the revised protocol reviewed and approved by designated member review (DMR). Absent unanimous consent to use DMR, the modified protocol must be returned for FCR at a convened meeting.
 

**or**
  - c. If all members of the IACUC are not present at a meeting, the committee may use DMR subsequent to FCR according to the following stipulations: All IACUC members have agreed in advance in writing that the quorum of members present at a convened meeting may decide by 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.

If all members are not present and the IACUC lacks written standard procedures as described above, the committee has the option to vote to return the protocol for FCR at a convened meeting or to employ DMR. If electing to use DMR, all members, including the members not present at the meeting, must have the revised research protocol available to them and must have the opportunity to call for FCR. A DMR may be conducted only if all members of the committee have had the opportunity to request FCR and none have done so. (PHS Policy IV.C.2)

- d. Minor modifications of an administrative nature, i.e., typographical or grammatical errors, required signatures, etc. may be confirmed by IACUC administrative/support personnel.
- If full-committee review (FCR) is not requested within a specified time frame, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, may be assigned to review those protocols and have the authority to approve, require modifications in (to secure approval) or request full committee review of those protocols.
  - Generally, DMR is conducted by the IACUC Chair and Attending Veterinarian.
  - Records of polling of members, to obtain concurrence to use the DMR method, are maintained in the IACUC protocol file and recorded in the minutes of the next convened IACUC meeting.
  - Other IACUC members may provide the designated reviewer(s) with comments and/or suggestions for the reviewer's consideration only, that is, concurrence to use the designated-member review (DMR) method may not be conditioned.
  - If multiple designated reviewers are used and modifications are required, each designated member will be sent an identical copy of the final modified protocol.
  - If multiple designated reviewers are used, their decisions must be unanimous; if not, the protocol will be referred for FCR.
  - The following are the possible outcomes of DMR:
    - a. Approval
    - b. Modifications Required to Secure Approval
    - c. Refer for Full Committee Review
  - Veterinarian Verification and Consultation may be used as follows:
    - The VVC process may not be used to add new procedures to a previously approved protocol or to modify existing procedures if the modification increases the opportunity for the animals' welfare to be compromised. The Attending Veterinarian (AV) may refer any request to the IACUC for review for any reason and must refer any request that does not meet these parameters. The changes that may be approved by VVC are to:
      - Changes in animal vendor, strain, sex or source or shipping destination
      - Change in anesthesia from/to ketamine/xylazine or isoflurane
      - Change in analgesics from/to ketorolac/ketoprofen/buprenorphine
      - Change in euthanasia method from/to CO2/cervical dislocation/euthanasia solution injection
      - Change in identification method from/to ear tag/ear punch/ tail or paw tattoo
      - Addition of animal euthanasia at BNL
      - Addition of blood or tissue sample timepoints at BNL

- o Change in ion, energy and/or dose rate (Consultation with NSRL Liaison Biologist and/or NSRL PI required)
    - o Increase in animal numbers
  - Records of the VVC are maintained in the IACUC protocol file and recorded in the minutes of the next convened IACUC meeting.
  - The following are the possible outcomes of VVC:
    - a. Approval
    - b. Modifications Required to Secure Approval
    - c. Refer for Full Committee Review
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:
- Review and approval of significant changes are handled in the same manner as new protocols. See Section III.D.6. above.
  - Examples of changes considered to be significant include, but are not limited to, changes:
    - a. in the objectives of a study
    - b. from non-survival to survival surgery;
    - c. resulting in greater discomfort or in a greater degree of invasiveness;
    - d. in the species or in approximate number of animals used<sup>1</sup>;
    - e. in Principal Investigator;
    - f. in anesthetic agent(s) or the use or withholding of analgesics;
    - g. in the method of euthanasia; and
    - h. in the duration, frequency, or number of procedures performed on an animal
- <sup>1</sup> Changes of less than 10% in the approximate number of animals used of mice of the genus *Mus* and rats of the genus *Rattus* that are bred for use in research only may, at the IACUC's discretion, be considered minor (not significant).
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:
- Principal Investigators are notified by a memo from the IACUC Chairperson and the IO is sent copies of the IACUC minutes.
  - If modifications are required to secure approval, the PI is notified in writing of the modifications required.
  - If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
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:
- Post Approval Monitoring – All ongoing activities are monitored continuously by the animal care and use staff and two protocols are randomly selected for compliance monitoring during each semi-annual inspection.

- All protocols involving non-USDA covered species are reviewed by the IACUC by FCR at least annually.
  - IACUC decisions regarding annual reviews are recorded in the IACUC meeting minutes which are reviewed and approved by the Committee at its next meeting.
  - Protocols are approved for a maximum of 36 months. That is, all protocols expire no later than the three-year anniversary of the initial IACUC approval.
  - If activities will continue beyond the expiration date, prior to expiration of the original or preceding protocol, a new protocol must be submitted, reviewed, and approved as described in Paragraph III.D.6. above.
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 may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or IV.C.1.a.-g. of the PHS Policy.
  - The IACUC may suspend an activity 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.
  - If the IACUC suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, the *Guide*, or the institution's Assurance, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation, in writing, to OLAW. Initial/preliminary reports may be made by telephone.
- E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:
1. Administration/management
    - The Manager of the Occupational Medicine Clinic (OMC), a New York State licensed physician specializing in Occupational Health, is responsible for the overall management of the Occupational Health and Safety Program for personnel involved in the care and/or use of laboratory animals. The Manager is involved in the planning and management of the program along with input from the Biology Department Environment, Safety and Health (ES&H) Representative and subject matter experts from the Safety & Health Services Division. The OMC is comprised of New York State licensed physicians, nurses and phlebotomists. OMC operations include administrative and medical services for staff and visitors.
  2. Scope
    - The Occupational Health and Safety Program covers all personnel identified on IACUC approved protocol, as well as Animal Care Staff and others who may have exposure to research animals.
    - Enrollment in the program is facilitated by the BNL Departmental Supervisor & ES&H coordinator who notify the OMC that an employee works with/or may have exposure to research animals. Notification is through submission to OMC of an electronic Job Assessment form (JAF) that describes the employee's work and essential job functions.
  3. Health Histories and Evaluations

- Employee's health records are kept strictly confidential and meet federal, state and local HIPAA regulations for personal health confidentiality. All who handle Personally Identifiable Information (PII) must complete the following required training courses: Information Security Awareness, Protecting Personally Identifiable Information and Systems specific training required for access to DOE Privacy Act Systems of Records (SORS). Hard copies of health records are kept in a file room which is attended all day and locked at night. The OMC itself is also locked at night and under 24-7 surveillance by BNL's police group via CCTV and motion sensors. The electronic portion of the employee's record is kept in a highly secure electronic health record that is password protected, behind a secure firewall on a dedicated server, and only accessible to authorized users within the OMC to clinical staff who have signed a confidentiality agreement. All OMC computers are also password protected, with login requiring 2 factor authentication using special "HSPD-12" ID badges. Records are covered by DOE's Privacy Act, with release of information only for specified official purposes, if mandated by law or upon the written authorization of the employee.
- OMC has established two categories of Brookhaven Lab Animal Facility (BLAF) Protocols.
  - a. Basic Animal Researcher (Vet staff, PI, Technician)
  - b. Short Term Animal Exposure (Summer students, guests, IACUC Members, security personnel and maintenance/custodial workers)
- For Basic Animal Researchers, pre-placement and annual health evaluations focus on medical, allergic and animal exposure related histories, discussion of potential infections and allergens, PPE's, required immunizations, followed by a complete physical examination by a physician or nurse practitioner.
- A complete physical examination will include measurement of vitals, hearing, vision, blood and urine tests, vaccinations ( if applicable), PPD, EKG, pulmonary function tests and any other test as deemed necessary.
- Any other individuals (summer students, guests, IACUC Members, security personnel and maintenance/custodial workers) are made aware of potential health related issues associated with the work at BNL via the BNL Work Planning and Control Processes as well as training and postings and discussion with the BLAF Manager. A sign is posted near the entrance to the BLAF describing steps to protect from exposure to allergens.
- Technical personnel working with animals are issued appropriate PPE. Clean work clothing is put on each morning and changed during the day as/if needed. Personnel are required to change out of their work clothing into street clothes before they go to lunch or home for the day. Change facilities, lockers, showers, hand washing facilities and toilets for animal care personnel are located within the animal facility.
- In the BLAF, eating and drinking non-alcoholic beverages are permitted in the lounge room. Eating and drinking are not permitted in any other area of the animal facility. Eating and drinking are not permitted in the research laboratories. Smoking is prohibited in all buildings.

#### 4. Hazard Identification and Risk Assessment

- As part of the Institutional Work Planning and Control Program, all experiments require submission and approval of an Experimental Safety Review (ESR). All hazards and associated controls are established as part of that process. An activity-level risk assessment is also performed as part of that process to ensure work is performed at the lowest practical risk level.

- Procedures for the use of hazardous agents in animals as well as all other applicable hazards are established by the Principal Investigator (PI), in consultation with the Attending Veterinarian, and with input from the Experimental Safety Review Team. The team includes members the Department's Environmental, Safety, and Health Representative (ESHR) as well as Worker Safety and Health, Radiological Control and Environmental Compliance Representatives that are assigned to the research departments.
- Procedures for handling animals exposed to or injected with hazardous agents when they are housed in the BLAF following an experiment are detailed in BLAF's standing operating procedures (SOPs) or other work planning documents (e.g. general or radiation work permit).
- All areas where animals are used and stored undergo a facility risk assessment. All hazards in the area are identified and posted in accordance with Institutional Policies.
- Procedures using radioactive material may require a Radiation Work Permit. This is determined by the Radiological Control Representative as part of the Experimental Safety Review Process. All animal users are appropriately trained and qualified before starting work to ensure the safe handling of these materials. Institutional policies and procedures mandate a specific process for the use of hazardous agents.
- Employees are required to immediately report any potential hazards or exposure to their supervisor and the Occupational Medicine Clinic.
- Exposure of employees to potential hazardous substances and/or pollutants is identified and a record of exposure is maintained by the Occupational Medicine Clinic.
- As part of the Work Planning process, if a potentially hazardous condition is identified, employees receive additional training before work begins.

#### 5. Procedures in Place to Alleviate Hazards and Minimize Risks

- Personnel are informed about occupational health considerations through training and medical surveillance as well as by verbal communication with the ESH staff, the Attending Veterinarian and the Occupational Health physicians.
- Potential hazards from animals used at BNL, including zoonoses and allergens, are detailed in the Basic training that all personnel are required to take.
- Safety Data Sheets are maintained in the BNL Chemical Management Database and available to all workers.
- Periodically, newsletters, emails and seminars focusing on a particular health problem, for example, allergies and Lyme disease, are published and distributed to all BNL employees.
- BNL provides required Personal Protective Equipment to workers (e.g. caps, eye/face protections, masks, coats, gloves).
- The Radiological Control Division (RCD) closely monitors exposures to radiation and potentially toxic materials following DOE Radiological Control Program requirements (10CFR830). Radiation dosimeters are issued to all Brookhaven employees who may potentially experience radiation exposure as mandated by RCD procedures and federal rules. All animal care personnel have attended radiation worker training

#### 6. Immunizations

- Rabies vaccine is offered to individuals with the potential to directly handle wildlife species.

- All employees covered by the Brookhaven Laboratory Animal Facility protocols as indicated in Item E(4) are required to have documentation of up-to-date Tetanus vaccination. Immunization status is assessed annually and Td/Tdap is offered as necessary. Short term employees are required to bring in a record of their immunization.

7. Precautions taken during pregnancy, illness or decreased immunocompetence

- At the time of their OMC physical examination, employees receive information sheets on risk of allergy or infectious diseases from animals and are encouraged to contact or come to OMC if they have any health concerns. Employees out for five or more days must be cleared for return to work by the OMC and a supervisor may also direct an employee to OMC if the supervisor or the employee have any concerns about the employee's ability to perform his/her job duties without significant risk to himself/herself or others. An employee may voluntarily declare her pregnancy to her department in which case any appropriate work restrictions will be discussed with the OMC.
- During training, personnel are advised that if they are pregnant, plan to become pregnant or have decreased immunocompetence, they should contact their healthcare professional. Any necessary accommodations will be worked out with the healthcare professional and HR.

8. Provisions for personnel who are not involved in animal care and/or use but nevertheless need to enter areas when animals are housed or used

- The required PPE and animal exposure information regarding allergies is posted at the entrance to the Facility or directly communicated with individuals. The Facility provides necessary PPE for all areas where animal species are present.
- Individuals will receive a facility briefing and be escorted as necessary. If work is prolonged or extensive, animals will be removed from the applicable rooms or areas.

9. Availability and procedures for treatment of bites, scratches, illness or injury

- BNL provides bite/wound kits and follow-up medical care.
- Medical care is available to all personnel who work with animals throughout the workweek.
- Acute illness, work-incurred injuries, including animal bites, etc., are immediately attended to by one of the occupational health physicians.
- Treatment, including tetanus immunizations, may be given as necessary. If the employee is sent home, the Laboratory may require an additional examination before the employee is permitted to return to work.
- After hours injuries are tended to by EMT's at BNL's Fire Rescue division with first aid, transport to the appropriate acute care facility, if needed, and follow-up at OMC.

10. Procedures/program for reporting and tracking injuries and illnesses

- Detailed records of illnesses and work-incurred injuries are on file in the Occupational Medicine Clinic. All BNL staff members who have contact with animals are involved in the program.

11. Other Pertinent Information Regarding the OH&S Program

- Brookhaven's Occupational Medicine Program is in full compliance with the Department of Energy Order for contractor occupational health services for all Laboratory employees.

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:

1. IACUC Members

- Each IACUC member will be provided with a copy of the following:
  - a. The PHS Policy for the Humane Care and Use of Laboratory Animals;
  - b. The National Research Council (NRC) Guide for the Care and Use of Laboratory Animals
  - c. This Assurance.
- All IACUC members undergo initial and triennial training by the IACUC Administrator. This training includes review of federal, state and local policies regarding use of animals, organization of the BNL animal care and use program, overview of the roles and responsibilities of IACUC member and investigators and IACUC review procedures.
- IACUC members also take the CITI IACUC Member Training.

2. Animal Care and Use Personnel

- All personnel involved in animal care and/or use, including students and visiting personnel, are given training and instruction in the humane care and ethical use of research animals.
- The training program is compliant with the Animal Welfare Act, Public Health Service Policy, and the Department of Energy policy on personnel.
- All personnel performing procedures using animals must be identified in the Institutional Animal Care and Use Protocol.
- A description of each individual's qualifications, experience and/or training with the specific animal species, model and procedures must be provided for IACUC review.
- Any person needing additional protocol-specific training will be identified during the review process and such required training must be completed prior to performing any animal manipulations.
- All personnel involved in animal care and/or use must complete the "Basic Overview of Laboratory Animal Care and Use" computer course and examination. This provides an introduction to federal, state and local laws that govern the use of animals in research and the consequences of non-compliance, as well as an orientation to the laboratory animal facility. This course addresses all items described in 9CFR, Part 2, Subpart C, Section 2.32(c). Specifically, as applicable, training and instruction of personnel includes guidance in at least the following areas:
  - a. Humane methods of animal maintenance and experimentation, including:
    - i. The basic needs of each species of animal;
    - ii. Proper handling and care for the various species of animals used by the facility;
    - iii. Proper pre-procedural and post-procedural care of animals; and
    - iv. Aseptic surgical methods and procedures;
  - b. The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;

- c. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;
  - d. Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act;
  - e. Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:
    - i. On appropriate methods of animal care and use;
    - ii. On alternatives to the use of live animals in research;
    - iii. That could prevent unintended and unnecessary duplication of research involving animals; and
    - iv. Regarding the intent and requirements of the Animal Welfare Act and USDA-APHIS Regulations
- A tour of the facility and opportunity for discussion of any questions with the Animal Facility Manager is also provided. Investigators have direct, i.e., face-to-face, interaction with the Attending Veterinarian.
  - All personnel are required to complete refresher training every two years.
  - Training in experimental methods and procedures, i.e., specific animal manipulations and techniques, is conducted based on the types of research being conducted at the institution and on a case-by-case basis. This training is accomplished with computer based modules and examinations, followed by individual hands-on training.
  - The Attending Veterinarian either conducts the training or certifies additional personnel that may also function as trainers.
  - Verification of previous training for personnel from other institutions may be accepted in lieu of BNL's required training. Acceptance of previous training in lieu of the Institution's training is solely at the IACUC's discretion.
  - All training is verified and documented in the Brookhaven Training Management System (BTMS) by the EBNN Training Coordinator. Documentation of all training will be maintained by the Institution for at least three (3) years and available to OLAW upon request.

#### **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**

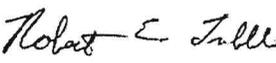
- A. This Institution will maintain for at least 3 years:
1. A copy of this Assurance and any modifications made to it, as approved by the PHS
  2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations
  3. Records of applications, proposals, 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, Robert Tribble.
  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, Robert Tribble.
  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**

<b>A. Authorized Institutional Official</b>	
Name: Robert Tribble	
Title: Deputy Director for Science and Technology	
Name of Institution: Brookhaven National Laboratory/Brookhaven Science Associates, LLC	
Address: <i>(street, city, state, country, postal code)</i> 400 Brookhaven Ave. Bldg. 460 PO Box 5000 Upton, NY 11973-5000	
Phone: 631 344-3177	Fax: 631 344-5803
E-mail: rtribble@bnl.gov	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature: 	Date: 08/31/2020

<b>B. PHS Approving Official</b> <i>(to be completed by OLAW)</i>	
<p>Venita B. Thornton, DVM, MPH Senior Assurance Officer Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6700B Rockledge Drive Suite 2500 - MSC 6910 Bethesda, Maryland 20892 Email: thorntov@od.nih.gov Phone: (301) 451-4208 Fax: (301) 480-3421</p>	
<p style="text-align: right;">Venita B. Thornton -S Digitally signed by Venita B. Thornton -S Date: 2020.09.03 13:34:01 -04'00'</p>	
Signature:	Date: September 3, 2020
Assurance Number: D16-00067 (A3106-01)	
Effective Date: September 3, 2020	Expiration Date: August 31, 2024

## VIII. Membership of the IACUC

Date: January 2020			
Name of Institution: Brookhaven National Laboratory			
Assurance Number: A3016-01			
<b>IACUC Chairperson</b>			
Name*: Timothy Green			
Title*: Natural Resources Manager			Degree/Credentials*: PhD
Address*: ( <i>street, city, state, zip code</i> ) 120 East Fifth Ave. Bldg. 860 PO Box 5000 Upton, NY 11973-5000			
E-mail*: <a href="mailto:tgreen@bnl.gov">tgreen@bnl.gov</a>			
Phone*: 631 344-3091		Fax*: 631 344-7334	
<b>IACUC Roster</b>			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Thomas Zimmerman	DVM, MPVM, DACLAM	Attending Veterinarian	Veterinarian
DB	AS, RRPT	Rad Control Tech	Non-Scientist
RF	MA	Retired Teacher	Non-Scientist, Non- Affiliated
PF	PhD	Biochemist	Scientist
DP	BS, MS	Staff Engineer	Scientist
AS	MS	Retired Teacher	Scientist, Non-Affiliated
NS	MBA	Manager, Env. Communications and Outreach	Non-Scientist
SS	MS	Project Coordinator	Non-Scientist
DM	BA	IACUC Administrator	Ex-officio, Non-voting
MP	BS, RLATG, CMAR, CPIA	Manager, Animal Facility	Ex-officio, Non-voting
PG	PhD	NASA Liaison	Ex-officio, Non-voting
CB	BA	Animal Facility	Ex-officio, Non-voting

\* 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.

<b>Contact #1</b>	
Name: Darcy Mallon	
Title: IACUC Administrator	
Phone: 631 344-3362	E-mail: mallon@bnl.gov
<b>Contact #2</b>	
Name:	
Title:	
Phone:	E-mail:

