BROOKHAVEN
NATIONAL LABORATORY

BROOKHAVEN NATIONAL LABORATORY

POLICY AND PROCEDURES

FOR THE CARE AND USE OF LABORATORY ANIMALS

Approved:	Tim Green	3/19/2021
	IACUC Chair	**Date**
Approved:	Robert E. Tuttle	3/22/2021
	Institutional Official	**Date**

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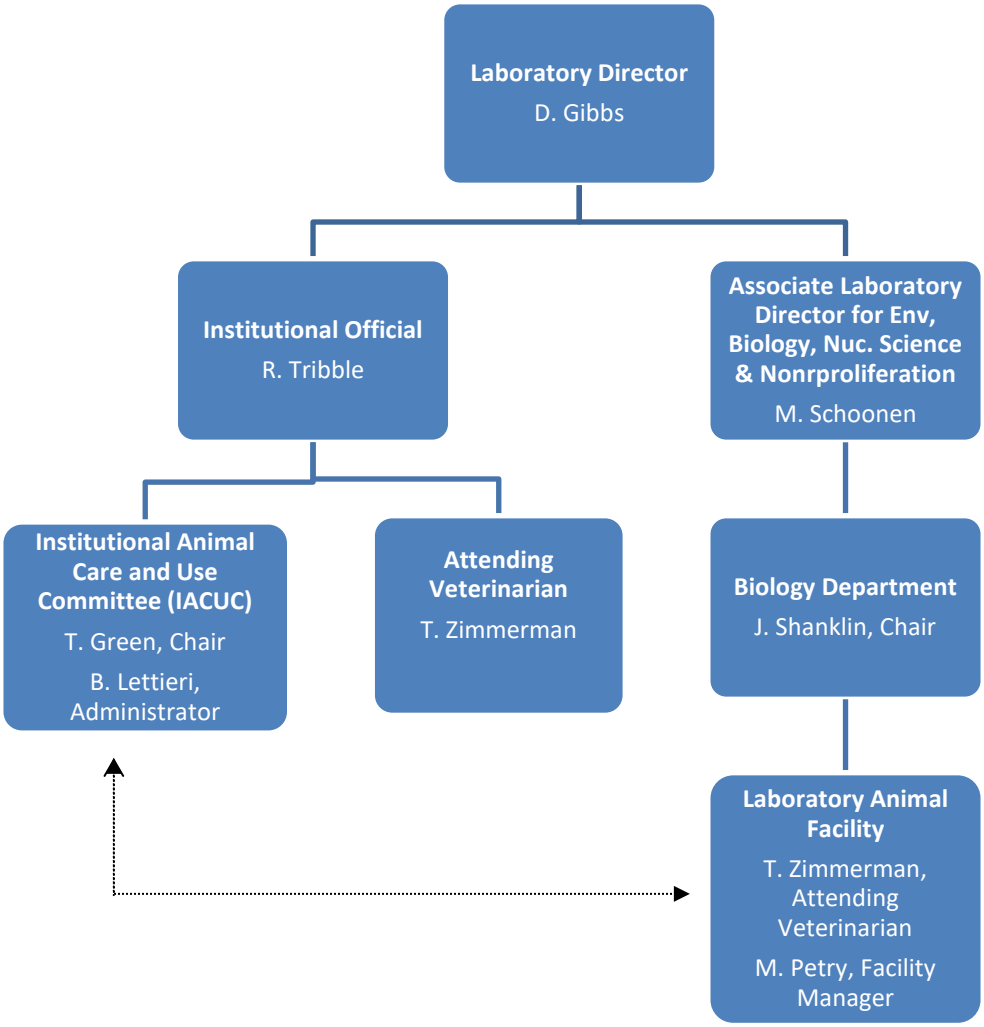
1.0 **ESTABLISHMENT OF THE BNL IACUC**

1.1 Brookhaven National Laboratory (BNL) is one of ten national laboratories overseen and primarily funded by the Office of Science of the U.S. Department of Energy. Brookhaven is operated and managed by Brookhaven Science Associates, which was founded by the Research Foundation for the State University of New York on behalf of Stony Brook University, and Battelle, a nonprofit applied science and technology organization. BNL is a multidisciplinary laboratory that operates cutting-edge large-scale facilities for studies in nuclear science, data science, particle physics, accelerator science and technology, quantitative plant science and quantum information science.

1.2 The Institutional Animal Care and Use Committee (IACUC) is established and authorized by the Laboratory Director in accordance with Federal policy. Its jurisdiction includes all research involving live vertebrate animals performed at or in conjunction with BNL and its employees, regardless of the Principal Investigator's (PI) appointment or relationship to BNL. The Laboratory Director will act as Institutional Official (IO), or may delegate this authority in writing. When an IO is delegated, that delegation will be renewed whenever there is a change in the Laboratory Director.

1.3 The IACUC is appointed by and reports to the IO.

1.4 While collaborating institutions maintain ownership of research animals, BNL has custodial responsibility for the care and housing of the animals while at BNL. This includes veterinary care, transport of animals between facilities and shipment to collaborating institutions, all of which comply with federal regulations.


Laboratory Director
D. Gibbs
Institutional Official
R. Tribble
Associate Laboratory Director for Env, Biology, Nuc. Science & Nonrproliferation
M. Schoonen
Institutional Animal Care and Use Committee (IACUC)
T. Green, Chair
B. Lettieri, Administrator
Attending Veterinarian
T. Zimmerman
Biology Department
J. Shanklin, Chair
Laboratory Animal Facility
T. Zimmerman, Attending Veterinarian
M. Petry, Facility Manager

2.0 **THE OFFICE OF RESEARCH ADMINISTRATION**

2.1 The Office of Research Administration (ORA) is authorized and established by the Laboratory Director

2.2 The ORA is responsible to the Laboratory Director and the Institutional Official for the IACUC

2.3 A mission of the ORA is to provide administrative support to the IACUC

2.4 With respect to the support to the IACUC, the goal of the support is to help assure that all research involving animals conducted at BNL complies with the following federal policies and guidance:

- The PHS Policy on Humane Care and Use of Laboratory Animals:
- The Guide for the Care and Use of Laboratory Animals:
- The American Veterinary Medical Association (AVMA) Panel on Euthanasia:
- Public Law 99-158, Section 495 "Animals in Research":
- New York State Department of Health Regulations, Subpart 55-1 "Approval of Laboratories and Institutions for Use of Living Animals and for Requisition and Allocation of Animals from Pounds"

3.0 ROLES & RESPONSIBILITIES ACCOUNTABILITIES & AUTHORITIES (R2A2s)

3.1 Institutional Official

Role

- To provide oversight for the institution's animal care and use program.

Responsibilities

- Sign the Assurance with the Office of Laboratory Animal Welfare (OLAW) to commit the institution to meet the requirements of PHS Policy
- Ensure the institution complies with all applicable animal welfare laws, regulations and policies, and commitments in its Assurance
- Appoint the Institutional Animal Care and Use Committee (IACUC)
- Appoint the Chair of the IACUC
- Receive semi-annual inspection reports from the IACUC
- In consultation with the IACUC, determine whether deficiencies are significant or minor
- Review and approve annual reports for the Office of Laboratory Animal Welfare (OLAW)
- Consult regularly with the IACUC Chair and IACUC Administrator
- Consult with the IACUC regarding suspensions of IACUC protocols and corrective actions; Report to regulatory and funding agencies as required by applicable regulations
- Ensure the institution maintains the required records for the specified period of time
- Ensure all personnel involved in animal care, treatment and use are qualified to perform their duties and that training and instruction in specific areas are provided to those personnel
- Ensure that the qualifications of personnel are reviewed with sufficient frequency to fulfill the institution's responsibilities

Accountabilities

- To Laboratory Director for the conduct of the animal care and use program and operation of the IACUC Authorities
- Sign the Assurance with OLAW
- Appoint the IACUC
- Allocate institutional resources as appropriate to support the Animal Care and Use Program
- Enact appropriate disciplinary mechanisms for personnel who fail to properly conduct animal research and report such actions to regulatory agencies
- May subject protocols that have been approved by the IACUC to further review and approval, but may not approve an activity that has not been approved by the IACUC
- Report suspension of IACUC protocols or protocol violations to appropriate regulatory agencies

3.2 **Attending Veterinarian**

Role

- To develop and implement an effective program of veterinary care for the institution

Responsibilities

- Serve as a member of the IACUC
- Advise IACUC on the recognition and palliation of pain, medical care of animals, aseptic surgery and postoperative care, multiple major survival surgery and ensuring veterinary care is available to mitigate animal pain and/or distress
- Review IACUC submissions to ensure that methods of experimentation, surgery, analgesia and euthanasia are appropriate
- Advise BLAF personnel on veterinary program issues
- Meet regularly with the IACUC Chair to assess BLAF operations and IACUC submissions
- Oversee investigator training program
- Direct or perform procedures to identify disease or etiologies in animals
- Prescribe treatments to ill animals
- Develop programs for quarantine and isolation, monitoring of vendors, monitoring of colony health, and routine vaccinations and parasite control
- Advise investigators on and assure proper use of methods to relieve or reduce pain and distress to animals
- Oversee pre-surgical preparation, surgical procedures and post-surgical care of animals
- Assure that animals are euthanized when appropriate and in an humane manner
- Assure that programs for disinfection, housing, nutrition, breeding and environmental enrichment are appropriate
- Work with safety personnel to assure safe use of biologic, radiologic and chemical hazards
- Advise investigators and the IACUC on the appropriateness of specific techniques and methods in animals, and the availability of alternative animals and non-animal models
- Advise IACUC and health professionals on aspects of the occupational health program

Accountabilities

- To the Institutional Official and the Biology Department Chair for the Veterinary Care Program
- To the Institutional Official and IACUC Chair as an IACUC member

Authorities

- Review IACUC protocols and continuing review applications and approve, as appropriate, for submission to the IACUC
- Review amendments to approved IACUC protocols and approve for submission to the IACUC if significant change or coordinate Designated Member Review and approval with the IACUC Chair if appropriate
- Perform Veterinary Verification and Consultation (VVC) for amendments, if appropriate
-
- Stop or interrupt an animal research study upon evidence of a hazard to the safety of study personnel
- Stop or interrupt an animal research study if an issue of animal welfare and/or protocol compliance arises

3.3 **IACUC Chair**

Role

- To oversee the coordination and implementation of effective, efficient systems for protocol and program review by the IACUC in compliance with regulatory policies.

Responsibilities

- Lead IACUC meetings and direct discussions
- Review the meeting minutes and reports for submission to the IO
- Report to the IO any activities that have been suspended by the IACUC or any serious or continuing protocol compliance problems or BLAF operations problems
- Meet regularly with the Attending Veterinarian to assess BLAF operations and IACUC submissions
- Meet regularly with the IO and IACUC Administrator
- Review amendments to approved IACUC protocols and approve for submission to the IACUC if significant changes are involved or coordinate Designated Member Review and approval with the Attending Veterinarian if appropriate
- Inform regulatory agencies of changes in IACUC membership
- With IACUC Administrator, interview potential IACUC members and recommend to IO

Accountabilities

- To the Institutional Official for IACUC operations

Authorities

- Coordinate Designated Member Review and approval with the Attending Veterinarian if appropriate
- Appoint Deputy Chair IACUC
- Stop or interrupt an animal research study upon evidence of an imminent hazard to the safety of study personnel
- Stop or interrupt an animal research study if an issue of animal welfare and/or protocol compliance arises
- Review and approve, if appropriate, modifications to protocols as authorized by the IACUC

3.4 **IACUC Members**

Role

- To participate as a member of the IACUC, the committee that oversees the institution's animal program, facilities and procedures and that reviews and approves every research protocol that involves the use of animals

Responsibilities

- Review, at least once every six months, the institution's program for humane care and use of animals, using the "Guide for Care and Use of Laboratory Animals" (the Guide) as a basis for this evaluation
- Inspect, at least once every six months, all the institution's animal facilities using the Guide as a basis for evaluation
- Review and investigate concerns involving the care and use of animals at the institution
- Make recommendations to the IO on any aspect of the institution's animal program, facilities or personnel training
- Review and approve, require modifications in (to secure approval), or withhold approval of proposed activities related to the care and use of animals
- Review and approve, require modification in (to secure approval), or withhold approval of proposed significant changes to approved IACUC protocols regarding the care and use of animals
- Prepare for, by reading the full agenda, and attend IACUC meetings

Accountabilities

- To the IO and IACUC Chair for IACUC operations

Authorities

- Stop or interrupt an animal research study upon evidence of a hazard to the safety of study personnel
- Authorize the IACUC Chair to grant full approval for conditionally approved submissions

3.5 **IACUC Administrator**

Role

- To establish and direct the operations of effective, efficient systems for protocol, facilities and program reviews by the IACUC in compliance with regulatory policy

Responsibilities

- Ex-officio, non-voting member of the IACUC
- Coordinate and schedule IACUC meetings, facility inspections and laboratory site visits by IACUC
- Promptly convey IACUC decisions to investigators in writing
- Coordinate and schedule reviews of institution's animal care and use program by outside agencies
- Act as a resource for investigators and IACUC members for regulatory issues and the status of protocols
- Prepare, maintain and update as required all institutional policy and procedure documents, forms and website
- Prepare semi-annual BLAF and laboratory inspection report for IACUC review and approval and submission to IO
- Screen IACUC submissions for accuracy and completeness and correspond with investigator if documentation is inaccurate and/or incomplete
- Prepare and distribute agenda to IACUC
- Ensure a quorum is present at every IACUC meeting
- Declare the loss of a quorum resulting in the suspension of official business if a sufficient number of members depart during a convened meeting
- Prepare IACUC meeting minutes
- Prepare memos for IACUC Chair's signature advising PIs of actions taken by IACUC at convened meeting
- Ensure that each approved IACUC protocol receives continuing review on the schedule established by the IACUC, but no less than annually
- Maintain all IACUC records and manage access to records
- Review field work studies approved by outside institutions for compliance with regulatory guidance
- Function as point of contact between the IACUC and regulatory agencies
- Establish and maintain all correspondence with accrediting and regulatory agencies involved in laboratory animal research and care, including annual reporting
- Develop and administer training for IACUC members and training for Principal Investigators on IACUC policies and procedures
- Review publications and other sources of information, including applicable local and national meetings, for information pertinent to the IACUC and Principal Investigators and distribute and/or discuss such information
- Participate in recruitment of IACUC members
- Process and maintain IACUC membership files including CVs
- Meet regularly with the IACUC Chair and IO

Accountabilities

- To the IACUC Chair for IACUC administration

- To the Institutional Official for IACUC operations
- To the Laboratory Director for ORA Administration

Authorities

- Terminate IACUC meeting upon loss of quorum

3.6 **IACUC Principal Investigator**

Role

- Design and conduct properly approved research studies involving animals

Responsibilities

- Know and adhere to federal and BNL rules and regulations governing research involving animals.
- Submit research protocols and amendments to approved protocols to the IACUC for approval prior to start of work
- Retain copies of all correspondence with the IACUC
- Submit substantive annual reports of the results of research conducted under IACUC protocols.
- Identify in the IACUC protocol all personnel working on the protocol, including other investigators, technicians, etc.
- Direct the work of staff members conducting research under IACUC protocols.
- Ensure that all protocol personnel are appropriately qualified and that training is kept up to date, including facility-specific training.
- Follow all Brookhaven Laboratory Animal Facility (BLAF) policies and procedures.
- Ensure that animals are properly handled and monitored during a procedure or surgery, as defined in the IACUC approved protocol, and ensure that research procedures that are followed are those defined in the IACUC approved protocol.
- Ensure that animals receive appropriate post-procedure care and monitoring.
- Ensure that animals are transported, on and/or off-site, by proper methods.
- Ensure that all approved protocols, amendments, and terminations are distributed to all protocol personnel, and that such personnel have read and understand the documents.
- Promptly report animal distress or unexpected death to Attending Veterinarian and/or BLAF staff.
- Report any unusual or adverse event or unanticipated problem to the IACUC.
- Maintain records according to Sponsor's requirements or for at least three years following completion of research.
- Make records available for inspection by the IACUC or other federal or state government agencies as required.

Accountabilities

- To the IACUC
- To the Department Chair
- To the Department Training Coordinator

Authorities

- Stop or interrupt an animal research study upon evidence of a hazard to the safety of study personnel
- Stop or interrupt an animal research study if an issue of animal welfare and/or protocol compliance arises

4.0 AUTHORITY AND RESPONSIBILITY OF THE IACUC

4.1 Authority

4.1.1 The IACUC has the authority to review the animal program and facilities, and to approve, to require modification as a condition of approval, to require additional information prior to committee review or prior to approval, and to withhold approval of proposed research that is within its scope of authority.

4.1.2 The IACUC has the authority to suspend, limit, or terminate any ongoing approved protocol.

4.1.3 The IACUC has the authority to determine whether or not a research activity is covered by these policies and procedures, and whether the activity requires review by the IACUC.

4.2 Responsibilities

4.2.1 To review, at least once every six months, the institution's program for humane care and use of animals, using the Guide as a basis for this evaluation;

4.2.2 To inspect, at least once every six months, all the institution's animal facilities using the Guide as a basis for evaluation;

4.2.3 To prepare reports of the IACUC evaluations defined above, and submit them to the Institutional Official;

4.2.4 To review concerns involving the care and use of animals at the institution;

4.2.5 To make written recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities or personnel training;

4.2.6 To review and approve, require modifications in (to secure approval), or withhold approval of those activities related to the care and use of animals and consider the following in such review:

4.2.6.1 Justification for the use of animals, the choice of species and the number of animals;

4.2.6.2 Assurance that the activity will be conducted in accord with the Animal Welfare Act insofar as it applies to the activity, and that the activity is consistent with the Guide unless acceptable justification for a departure is presents;

4.2.6.3 Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design;

4.2.6.4 Procedures do not unnecessarily duplicate previous experiments;

4.2.6.5 Procedures that may cause more than momentary pain or distress to animals shall be performed with appropriate sedation, analgesia or anesthesia, unless the use of such pain relief measures is contraindicated for scientific reasons and is justified in writing by the PI;

4.2.6.6 Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved for scientific reasons shall be euthanized at the end, or if appropriate, during the procedure;

4.2.6.7 Living conditions for the animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding and daily 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. All exceptions to the Guide for housing, feeding and care must be justified by the PI and approved by the IACUC;

4.2.6.8 Medical care for animals will be available and provided as necessary by a qualified licensed veterinarian;

4.2.6.9 Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures and such training and qualifications will be documented;

4.2.6.10 Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

4.2.7 Report any unanticipated problem involving risk to an animal or any instance of serious, or continuing noncompliance with OLAW or any involuntary suspension/termination of a protocol to OLAW and the research sponsor.

5.0 RECRUITMENT, TRAINING, ORGANIZATIONAL STRUCTURE AND MEMBERSHIP

5.1 IACUC Recruitment and Training

5.1.1 IACUC members are recruited from BNL employees, as well as neighboring institutions and the local community. Prospective IACUC members are interviewed by the IACUC Chair and/or the IACUC Administrator, and their credentials are reviewed by both. The IACUC Chair and Administrator then, if appropriate, recommend to the IO that the individual be appointed to the IACUC. The IO sends a letter of appointment.

5.1.2 When an individual accepts an appointment to the IACUC, the IACUC Administrator sends a letter explaining the operations of the IACUC and includes links to the following documents: the BNL/NIH Assurance, the OLAW "Public Health Service Policy on Humane Care and Use of Laboratory Animals" and the National Research Council "Guide for the Care and Use of Laboratory Animals".

5.1.3 The IACUC Administrator provides new members with an orientation/training session prior to their first IACUC meeting. A refresher of this training is given every two years. New IACUC members also take the CITI Essentials for IACUC Members, which is good for three years.

5.1.4 The BNL Continuing Education policy provides new materials regarding updates on animal research policies, as well as educational seminars and lectures given at BNL throughout the year. The IACUC Administrator, Chair and IACUC members attend various national meetings throughout the year, and disseminate any new information to the IACUC members and investigators as appropriate.

5.2 Appointment of Committee Members

5.2.1 The Chair of the IACUC shall be appointed to a two to three-year, renewable term by and shall report directly to the IO.

5.2.2 A Deputy Chair shall be appointed by the IACUC Chair and serve as the Chair in his/her absence.

5.2.3 The IO shall appoint all members of the IACUC to a two to three-year, renewable term.

5.3 Composition of the IACUC

5.3.1 Membership shall be in accordance with applicable federal policies:

5.3.1.1 shall be comprised of one Chair and at least four additional voting members;

5.3.1.2 shall include at least one doctor of veterinary medicine;

5.3.1.3 shall include at least one non-scientist;

5.3.1.4 shall include at least one practicing scientist experienced in research involving animals;

5.3.1.5 shall include at least one member who is not now, nor was, within the past five years, affiliated with BNL and who is not part of the immediate family of a person who is affiliated with BNL;

5.3.2 Committee membership shall include the BLAF Manager as an ex-officio, non-voting member to serve as a liaison between the BLAF and the IACUC and the NASA Liaison as a non-voting, ex-officio member to serve as a liaison between NASA and the IACUC.

5.3.3 The Committee shall be sufficiently qualified through the experience, expertise and diversity of its members, including consideration of race, gender, and cultural background and sensitivity to such issues as community attitudes, to permit complete and adequate review of research activities conducted by BNL.

5.3.4 The Committee shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

5.3.5 The IACUC shall have the option to invite individuals with competence in special areas to assist in reviewing of issues which may require expertise beyond, or in addition to, the expertise available on the IACUC. Such "specialists" shall not have voting rights.

5.4 **IACUC Membership Change Criteria**

5.4.1 The IACUC Chair and/or members may be removed from the IACUC for cause, as determined by the IO, or for administrative reorganization of the committee.

5.4.1.1 Causes for removal from the committee may include, but are not limited to: inappropriate personal conduct, poor attendance or inadequate participation in IACUC activities, or repeated inadequate performance of assigned IACUC duties.

5.4.1.2 Administrative reorganization of the committee may be required from time to time to maintain an effective compositional balance as the membership of the IACUC changes due to expirations of membership terms and withdrawal or retirement of members from the committee.

5.5 **Non-Affiliated Members**

5.5.1 All non-BNL members are indemnified by a clause in the Prime Contract with DOE.

5.5.2 All non-BNL members are reimbursed $50 per meeting attended.

5.6 **Occupational Health and Safety Program**

5.6.1 A brief synopsis explaining the occupational health concern of exposures to animal allergens and controls that can be taken will be posted at the entrance of the animal facility for all visitors to read before entering. Any concerns by the visitor can be addressed by the Occupational Medical Clinic or the Safety and Health Services Division.

6.0 **QUORUM AND VOTING**

6.1 A **quorum** shall consist of a majority of the voting members of the Committee. A quorum is required for protocol review and suspension votes. 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 (see 6.4). Members may participate via conference call.

6.2 **Voting privileges** shall be limited to those members present at the meeting. Alternates may not vote if the primary member is present. Proxy votes are not accepted. A majority vote is required for any IACUC determination.

6.3 **Abstentions**: A member may abstain from voting on a protocol. The abstention will be included in the minutes of the meeting.

6.4 **Conflict of Interest:** If a member has, or is perceived to have, a conflict of interest with the matter under review, they must recuse themselves from voting and may be required to leave the room while the IACUC is voting.

6.5 **Minority Views**: All minority views of the semi-annual report shall be recorded and transmitted in the semi-annual report to the Institutional Official.

7.0 **MEETING SCHEDULE AND AGENDA PREPARATION**

7.1 **Meeting Schedule**

7.1.1 IACUC meetings are scheduled to be held once a month. Meetings may be held by teleconference. Any use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24th, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.

7.1.2 Members are polled prior to each meeting to ensure a quorum. There must be a quorum on each vote excluding members who will be required to recuse themselves due to conflict of interest.

7.1.3 The IACUC Chair, Administrator, a Principal Investigator or IACUC member may request an interim meeting, which may be called at the IACUC Chair's discretion.

7.2 **Conduct of the Meetings**

7.2.1 Items are reviewed in the order in which they appear in the Agenda.

7.2.2 Principal Investigators may request to be present to explain aspects of initial applications during a meeting should the committee desire; however they must absent themselves during discussion and voting on their protocol.

7.2.3 Voting is done in a closed session.

7.3 **Preparation of the Agenda**

7.3.1 The Agenda is prepared by the IACUC Administrator

7.3.1.1 The IACUC Administrator ensures that all PIs are notified of an Annual/Triennial Review at least two months in advance of the protocol expiration date.

7.3.1.2 The IACUC Administrator collects all items from PIs for Initial, Amendment, Annual and Triennial Reviews and compiles the Agenda.

7.3.1.2.1 The Agenda includes the minutes from the previous meeting and may also contain educational information beneficial to the IACUC.

7.3.1.2.2 The Agenda includes all relevant documentation for each protocol under review whether Initial, Annual, Triennial or Amendment.

8.0 COMMITTEE RECORDS AND MINUTES

8.1 Records Storage

8.1.1 All administrative records of the IACUC are maintained in the ORA Office.

8.1.2 All active protocol files are maintained in the ORA Office.

8.1.3 Access to these offices is restricted to designated personnel and the rooms are secured when the staff is absent.

8.1.4 Records considered to be inactive are filed in the BNL Record Holding Area and are held for a minimum of 75 years.

8.2 Protocol-Specific Records.

8.2.1 Each Protocol is assigned a unique number by the IACUC Administrator. Numbers are assigned sequentially.

8.2.2 Records for each protocol, including all documentation reviewed by the IACUC, and correspondence relating to the protocol, as well as the relevant portions of minutes of the IACUC meeting, are maintained in an individual protocol file.

8.2.3 Protocols are filed numerically.

8.3 Minutes and Agendas

8.3.1 Minutes are taken at the meeting and are as inclusive as possible to record the true breadth of discussion by the IACUC.

8.3.1.1 Minutes shall include the time of meeting, voting and alternate members present, the arrival and departure of members during the course of the meeting.

8.3.1.2 All votes are recorded in the minutes listing number for, against and abstaining, along with major discussions and any conditions for approval.

8.3.2 Minutes from the previous meeting are included with the Agenda for IACUC members to review.

8.3.2.1 Any corrections/comments to the minutes are noted in the minutes of the next meeting.

8.3.2.2 The minutes are corrected accordingly and are then considered final.

8.3.2.3 Copies of the finalized minutes are sent to the Biology Department Chair and the IO.

8.3.3 Copies of the finalized minutes are filed chronologically and are maintained as noted in section 8.1.

8.3.4 Distribution of the minutes is limited to the IACUC, the Institutional Official and the Biology Department Chair.

8.4 Educational Materials

8.4.1 Educational materials, including the OLAW “Public Health Service Policy on Humane Care and Use of Laboratory Animals” and the National Research Council “Guide for the Care and Use of Laboratory Animals”

are distributed to each IACUC member and are also available at the ORA Office and the BLAF.

8.4.2 Current articles of interest pertaining to animal research are distributed to IACUC members and PIs as applicable.

8.5 **IACUC Master List**

8.5.1 The IACUC Master List is maintained in a database containing current information on all protocols.

8.5.2 The IACUC Administrator maintains the database.

8.5.2.1 The data include the protocol number, approval date, expiration date, Principal Investigator, protocol title, approved participants, animal species, number per year and funding source.

8.5.3 A printout of the Master List is posted on the IACUC SharePoint site and accessible to BLAF staff.

8.5.3.1 The BLAF Manager relies on this document to insure that (i) the Principal Investigator is conducting an approved study, and (ii) the participating staff has been properly approved.

8.6 **Assurance**

8.6.1 The original, signed copy of the Assurance, and any related correspondence, is maintained in the ORA Office.

8.7 **Records of Accrediting Body Determinations**

8.7.1 All records of accrediting body determinations, and any related correspondence, are maintained in the ORA Office.

8.8 **Records of Semi-Annual Reports and Recommendations**

8.8.1 All records of semi-annual reports and recommendations, and any related correspondence, are maintained in the ORA Office.

9.0 PROTOCOL AND REVIEW CATEGORIES

9.1 Protocol Categories

9.1.1 **IACUC Protocol:** A study must be reviewed by the IACUC if it involves live, vertebrate animals.

9.1.1.1 For research involving live, vertebrate animals that is to be carried out under a Cooperative Research and Development Agreement (CRADA), a stand-alone IACUC protocol shall be submitted that will serve to appropriately separate the results and other proprietary information about that project from research carried out under other programs.

9.1.2 **Field Studies:** Field research studies that involve contact with vertebrate animals, and are funded and conducted by an outside institution, shall be covered by an IACUC approved protocol. In lieu of preparing a BNL protocol, an investigator may submit an IACUC approved protocol and documentation of approval from an outside institution to the ORA. The IACUC Administrator and Chair will review the protocol to ensure compliance with guidance set forth in the Guide. Any questions raised in this review will be brought to the attention of the Attending Veterinarian to determine whether the protocol requires additional review and/or revision to be in compliance with the regulations. To keep the IACUC informed of such studies, a summary of the protocol will be provided to the IACUC as part of the agenda for the next regularly scheduled meeting.

9.13 **Exempt Research:** A study is considered to be Exempt if it does not involve live, vertebrate animals.

9.2 Protocol Review Categories: Protocols are reviewed under the following categories:

9.2.1 **Preliminary ORA Review**: This review determines if the protocol is under the jurisdiction of IACUC regulations and ensures the protocol package is complete and accurate.

9.2.2 **Initial Review**: Following the above Preliminary Review, an initial protocol is forwarded to the IACUC for review.

9.2.3 **Amendment Review**: This review is required whenever a Principal Investigator wishes to amend, change, modify or otherwise alter any procedures under an approved protocol.

9.2.4 **Continuing Review**:

9.2.4.1 Each protocol must be reviewed by the IACUC at least once per year.

9.2.4.2 At the time of an Initial, Triennial or Amendment Review, the IACUC shall determine an appropriate approval period that shall not exceed one year, but which may be of shorter duration either at the request of the PI or as a result of other concerns arising during protocol review which mandate a shortened approval period

9.2.5 **Triennial Review:** Every three years, each continuing protocol must be re-submitted as a new protocol and undergo an Initial Review.

9.2.6 **MIRC Review:** Protocols that involve USDA covered species will undergo additional review by the Modified Institutional Risk Committee.

10.0 IACUC REVIEW

10.1 All protocols or amendments that involve live vertebrate animals must be reviewed by the IACUC in one of the following ways:

10.1.1 **Full Committee Review**

10.1.1.1 All Initial, Annual and Triennial protocols are given full committee review.

10.1.1.2 Amendments may undergo Designated Member Review or Veterinarian Verification and Consultation.

10.1.2 The decision of a full committee review vote shall be one of the following and shall be in writing:

10.1.2.1 **Approval:** The protocol can be initiated or continued.

10.1.2.2 **Modifications required to secure approval:** The protocol is approved pending the Principal Investigator providing clarification of issues. Evidence of compliance with IACUC conditions must be provided in writing by the Principal Investigator to the IACUC Administrator. Minor administrative changes may be made by the IACUC Administrator with written concurrence from the PI. For minor modifications, the IACUC Chair and/or Attending Veterinarian are designated by the IACUC as the Designated Member(s) to review the response and grant final approval. Designated Member Review procedures listed below will be followed. If the modifications required are considered to be substantial, the response will be reviewed by full committee.

10.1.2.3 **Approval withheld:** The IACUC has determined the protocol cannot be approved

10.2 **Designated Member Review**

10.2.1 Designated Member Review may be requested for changes to an approved protocol through the submission of an amendment to the Chair and AV through the IACUC Administrator.

10.2.1.1 Designated Member Review will not be used for initial, annual or triennial reviews to an approved protocol.

10.2.1.2 Whether the proposed amendment warrants submission to the IACUC for Designated Member Review is determined by the IACUC Chair in consultation with the Attending Veterinarian.

10.2.2 The procedure for Designated Member Review is as follows:

10.2.2.1 A Preliminary Review is done as described in Preliminary Review.

10.2.2.2 The amendment is reviewed by the IACUC Chair, Attending Veterinarian and NASA Liaison, if applicable.

10.2.2.3 If Designated Member Review and Approval is appropriate, all IACUC members are provided with information regarding the proposed amendment, including the IACUC Protocol number, protocol title, name of the Principal Investigator and the nature

of the proposed amendment and a deadline date for requesting a full review.

10.2.2.4 Any IACUC member may request Full Committee Review for the proposed amendment. If any such request is made, the amendment will be reviewed at the next regularly scheduled IACUC meeting and the PI will be notified of the reason for the request.

10.2.2.5 If no IACUC member requests full review and a majority of the members have responded, the amendment is approved by the IACUC Chair using the Designated Member Approval Form.

10.2.2.6 In conducting a Designated Member Review, the IACUC Chair may exercise all of the authority of the IACUC except that the Chair may not disapprove the proposed addenda. A research activity may be disapproved only after Full Committee Review.

10.2.2.7 The decision of the DMR may be one of the following:

- Approval
- Modifications Required to Secure Approval
- Refer for Full Committee Review

10.2.2.8 Records of polling of members to obtain concurrence to use the DMR method are maintained in the protocol file.

10.2.2.9 Other IACUC members may provide the designated reviewer(s) with comments and/or suggestions for the reviewer's consideration, but the designated-member review (DMR) method may not be conditioned.

10.2.2.10 If multiple designated reviewers are used and modifications are required, each designated member will be sent an identical copy of the final modified protocol.

10.2.2.11 The Principal Investigator, BLAF Manager and applicable Facility personnel are notified by Approval Memos.

10.2.2.12 The action on the amendment is included in the agenda for the next IACUC meeting as "Actions Taken Since the Previous IACUC Meeting".

10.3 **Administrative Review**

10.3.1 Specific significant changes may be handled administratively in consultation with the Attending Veterinarian by Veterinarian Verification and Consultation (VVC). Consultation with the AV must be documented. The 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 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 changes that may be approved by VVC are to:

10.3.1.1 Changes in animal vendor, strain, sex or source or shipping destination
10.3.1.2 Change in anesthesia from/to ketamine/xylazine or isoflurane
10.3.1.3 Change in analgesics from/to ketorolac/ketoprofen/buprenorphine
10.3.1.4 Change in euthanasia method from/to CO2/cervical dislocation/euthanasia solution injection
10.3.1.5 Change in identification method from/to ear tag/ear punch/ tail or paw tattoo
10.3.1.6 Addition of animal euthanasia at BNL
10.3.1.7 Addition of blood or tissue sample timepoints at BNL
10.3.1.8 Change in ion, energy and/or dose rate (Consultation with NSRL Liaison Biologist and/or NSRL PI required).
10.3.1.9 Increase in animal numbers
10.3.1.10 Change in room temperature

Anesthetics

Ketamine/Xylazine
Mouse – Ketamine = 90-120 mg/kg; Xylazine = 5-10 mg/kg IP
Rat – Ketamine = 40-80 mg/kg; Xylazine = 5-10 mg/kg IP
Isoflurane
Mouse/Rat – 5% induction, 1-3% maintenance
Pentobarbital
Mouse – 40-85 mg/kg IP
Rat – 30-50 mg/kg IP

Analgesics

Ketoprofen
Mouse – 4-6 mg/kg SC
Rat – 5 mg/kg SC

Ketorolac
Mouse/Rat – 5-7.5 mg/kg SC
Buprenorphine
Mouse/Rat – 0.05-0.1 mg/kg SC

10.3.2 Changes that may be handled administratively by the IACUC Administrator include:
- 10.3.2.1 Correction of typographical errors
- 10.3.2.2 Correction of grammar
- 10.3.2.3 Contact information updates
- 10.3.2.4 Change in personnel, other than the PI. There must be an administrative review to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs, and meet other criteria as required by the IACUC.
- 10.3.2.5 Increase in animal numbers less than 10% of original number requested

10.3.3 The Principal Investigator, BLAF Manager and applicable Facility personnel are notified by Approval Memos.

10.3.4 The action on the amendment is included in the agenda for the next IACUC meeting as "Actions Taken Since the Previous IACUC Meeting".

10.4 **Grant Submission Review**

10.4.1 No grant award can be made without IACUC approval if animal research is proposed in the application.
- 10.4.1.1 If work is being performed at another institution, the institution must be PHS Assured. The grant face page should reflect the collaborating institution's IACUC approval date.
- 10.4.1.2 If tissues/samples are being used at BNL that are byproducts of other research or are available commercially, no BNL IACUC review and approval is required.

10.4.2 The "Just in Time" NIH policy for grant applications applies at BNL.
- 10.4.2.1 When a PI is notified by NIH that his/her grant application has been funded, the PI must submit the grant application and an initial protocol or amendment to the ORA.
- 10.4.2.2 The ORA Administrator will have the grant application and IACUC submission reviewed using a primary reviewer system.

10.4.3 The submission will be processed as an Initial Application or Amendment.

11.0 INITIAL PROTOCOL PREPARATION AND REVIEW PROCEDURES

11.1 Preparation

11.1.1 For a new protocol, PI obtains an IACUC Protocol form from the IACUC website http://www.bnl.gov/ora/IACUC.asp .

11.1.2 The PI must be familiar with federal and BNL regulations: http://www.bnl.gov/ora/IACUC.asp

11.1.3 The PI should confer with the AV during preparation of a protocol.

11.2 Preliminary Review:

11.2.1 All submissions receive a Preliminary Review by the IACUC Administrator to ensure that the protocol requires IACUC review and the application is complete.

11.2.1.1 Investigators will be notified upon submission if the protocol has the potential to undergo review by the MIRC.

11.2.2 **Full Committee Initial Review Procedures**

11.2.2.1 Following a determination that the protocol requires IACUC review, the IACUC Administrator reviews the Package for completeness (including IACUC approvals from other institutions, if applicable, and signatures of the PI and the PI's Department) and accuracy and assigns a number to the protocol.

11.2.2.2 The IACUC is mailed a copy of the protocol one and one-half weeks before the meeting as part of the Agenda.

11.3 Full Committee Review Procedures

11.3.1 A quorum must be present for all deliberations and votes.

11.3.2 Consultants may be invited to assist the IACUC in review of complex issues; however, they will not have voting privileges. Subcommittees may also be formed to address complex issues.

11.3.3. The minutes, recorded by the IACUC Administrator, must include discussions about the protocol in sufficient detail so as to reflect the depth of the consideration by the committee.

11.3.4 The following elements are considered in the IACUC review:

11.3.4.1 Hypothesis and specific aims;

11.3.4.2 Species and number of animals required and justification of same;

If animals are to be transported to BNL from another institution's animal facility, a recent health report from the facility must be submitted to the BLAF Manager at least two weeks before the planned experiment.

11.3.4.3 Justification of species and why work can't be done in a lower phylogenetic species;

11.3.4.4 Where animals will be housed and unusual housing and husbandry requirements including restriction of food or water;

I*nvestigative staff must be responsible for feeding all animals, weighing the correct amount of food, logging each feeding, and adjusting the ration as needed to maintain the rodent at the desired weight.*
Whenever possible, rodents are group housed. Unless scientifically justified, same sex animals shall be housed in compatible groups. Exceptions to this policy must be scientifically justified. Interim approval can be granted by the AV, pending review and full approval by the IACUC.

11.3.4.5 Adequacy of training and experience of personnel in the procedures used;
11.3.4.6 Training courses required;
11.3.4.7 All manipulations and experimental procedures;
11.3.4.8 Justification of food/water deprivation and/or prolonged or unusual restraint, if performed;
11.3.4.9 Literature search for alternatives to pain/distress;
11.3.4.10 Statement of how procedures have been refined to reduce pain/distress/morbidity and whether death is used as an endpoint;
11.3.4.11 List of all chemical agents used for sedation, analgesia and anesthesia including doses and route of administration;
11.3.4.12 Description of surgical procedures and post-surgical monitoring;
11.3.4.13 Description of anesthesia and anesthetic recovery monitoring;
11.3.4.14 Description and justification of multiple major survival surgeries;
11.3.4.15 Criteria and process for timely interventions, removal of animals from a study, or euthanasia if painful or stressful outcomes are encountered;
11.3.4.16 Method of euthanasia or disposition of animal;
11.3.4.17 Safety of working environment for personnel;
11.3.4.18 PI's assurance that the work does not involve unnecessary duplication of efforts;
11.3.4.19 Shipping procedures, if applicable
11.3.4.20 IACUC approval from other institutions, if so required;
11.3.4.21 The approval period.
11.3.4.22 Agents to be administered to animals:

- Protocols may be approved that include specific categories/classes of drugs to be administered, with the exception that Schedule 1 and Schedule 2 DEA regulated compounds are to be specifically and individually identified in the protocol and approved by the IACUC.

- Each continuing review of the protocol must include a complete list of the agents and doses administered over the course of the approval period.
- For any substance that is to be administered at concentrations exceeding the ED50, IACUC approval must be obtained in advance of using the compound.
- Protocols involving Schedule I or Schedule II compounds must list each compound to be used and use of Schedule I compounds must be approved by the BECS Department prior to IACUC review and approval.

11.4 **Notification of Determination**

11.4.1 The IACUC Administrator forwards the determination of the IACUC to the PI in an Approval Memo.

11.4.1.1 **Approved**

11.4.1.1.1 The Approval Memo sent to the PI includes the following: The date of IACUC approval; The approval period; A statement that the approval is given only for the protocol submitted and that any changes must be approved by the IACUC prior to being implemented; A statement that all research outlined in this protocol must be carried out under approved Experimental Safety Review(s) (ESR) and that the application must contain the same information as that listed in the approved ESR; A statement that it is the PI's responsibility to ensure that all individuals working on the protocol have been listed on an appropriate ESR and that their training is up to date;

11.4.1.1.2 A copy of the Approval Memo is also sent to the BLAF Manager, applicable Facility ESR Coordinator and Facility Manager.

11.4.1.2 **Modifications required to secure approval**

11.4.1.2.1 A memo listing the conditions to be met or questions to be answered is sent to the Principal Investigator by the IACUC Administrator.

11.4.1.2.2 The memo indicates whether the IACUC has authorized the IACUC Chair as the Designated Reviewer to review the PI's response and grant full approval if the response is acceptable or if the protocol must undergo Full Committee Review.

11.4.1.2.3 If the response must go back to Full Committee, the Principal Investigator is informed that no work may begin until the conditions are satisfied and the full IACUC has approved the conditions.

11.4.1.2.4 The PI is also notified of the due date for response in order for the protocol to be reviewed by the full committee at the next IACUC meeting.

11.4.1.2.5 All IACUC members must agree in writing that the quorum of members of the IACUC present at a convened meeting may decide by unanimous vote to use DMR subsequent to full board meeting when modification of a protocol or amendment to a protocol is needed to secure approval. Provided, however, that any member of the IACUC may, at any time, request to see the revised protocol and/or request full board review of the protocol.

11.4.1.3 **Approval withheld:**

11.4.1.3.1 A memo is sent to the PI listing the reasons for withholding approval.

11.4.1.3.2 The Principal Investigator has the right to respond in writing or in person to the IACUC.

11.5 Further BNL review and approval may be required, but BNL officials may not approve animal research that has not been approved by the IACUC.

11.6 **MIRC Review**

11.6.1 If the protocol involves a USDA-regulated species and the IACUC approves the protocol, the proposal will be forwarded to the Modified Institutional Risk Management Committee (MIRC) for further review. Laboratory and IACUC approval will be withheld until the MIRC review process is complete and Laboratory Director approval is granted.

11.6.2 Information to be sent to the MIRC by the IACUC Chair and/or Administrator includes:

11.6.2.1 A short 1-2 page description of the project, written with sufficient detail in non-technical language, that includes a description of the research, its goals and expected scientific impact, the type and number of species, the reason these particular species were chosen, and their status at the conclusion of the work. This summary will be prepared by the IACUC Chair and/or Administrator with input solicited from PI and should include the Title, IACUC Protocol number and name of Principal Investigator.

11.6.2.2 If a more in-depth review by the MIRC is requested, a copy of the PI's project grant proposal and associated peer review documentation is to be provided by the PI to the MIRC via the IACUC Chair and/or Administrator.

11.6.3 The IACUC will notify the PI of the decision to either accept or reject the proposal. Full IACUC approval will be granted if the MIRC accepts the proposal.

11.7 **PI Tracking**

11.7.1 The IACUC Administrator will maintain a list of protocol violations that will include Principal Investigators and any IACUC determinations. The IACUC will review this list when applicable.

11.8 **DOE Notification**

11.8.1 A list of animal use projects (small mammals, e.g., mice and rats) funded by DOE and non-DOE sponsors will be maintained and provided to SC/HQ through BHSO in a mid- and end-year report using the *Projects Involving Animal Use at SC Laboratories* form (Attachment 1). Projects using larger mammals (e.g., pigs, rabbits, dogs) will be forwarded to DOE SC for review and concurrence/non-concurrence that the work is acceptable to be performed at BNL using the *SC Institutional Review: Non-DOE Funded Work Proposal Involving Animal Use* form (Attachment 2). The IACUC will withhold approval of initial protocol submissions for protocols using larger mammals until concurrence has been received.

11.9 MOU

11.9.1 If a User requests a MOU, the BNL MOU form will be completed, signed by the BNL IACUC Chair and sent to the GUV Center to be attached to the User's University User Agreement.

12.0 AMENDMENT TO AN APPROVED PROTOCOL

12.1 A Principal Investigator must receive approval from the IACUC any time they wish to deviate from the protocol originally approved by the IACUC. No change in protocol can be initiated until the IACUC has approved the change.

Amendments may be reviewed either by full-committee review by a convened quorum of the members of the IACUC, or Designated Member Review by one or more members, employed only after all voting members have been provided an opportunity to call for full-committee review.

Significant amendments include, but are not limited to, a change in scope or PI of the protocol, addition of a surgical procedure, any change that would increase pain/distress to an animal, addition of a new species, change in method of euthanasia or addition of food or water restriction.

12.2 **Assurances of the Amendment Process**: The following procedures assure that proposed changes in research protocols are promptly submitted to the IACUC and are not implemented until IACUC approval is given:

12.2.1 Each Principal Investigator is notified of this policy with each approved protocol and each is required to attest to their commitment to the policy in the initial Application.

12.2.2 The BLAF Manager has substantial control of the laboratory animals, including control over the animal housing, care and feeding, and ordering of new animals. If s/he feels there is a violation, s/he shall report his/her concerns immediately to the AV or IO.

12.3 **Procedures for an Amendment Review:**

12.3.1 A Preliminary Review is done to determine whether a Full Committee Review is necessary or whether Designated Member Review is acceptable.

12.3.2 Addenda determined to require a Full Committee Review are processed as follows:

12.3.2.1 The Amendment Package, consisting of a completed Amendment Form including description of the amendment, justification for the amendment, species and number requested, justification for the number requested, and the method of anesthesia and/or euthanasia is submitted by the Principal Investigator to the IACUC Administrator.

12.3.2.2 The IACUC Administrator reviews the package for completeness and accuracy.

12.3.2.3 The package is included in the agenda for the next IACUC meeting.

12.3.2.4 The IACUC's review and approval process of an amended protocol is the same as for an Initial Review.

12.3.2.5 The approval period remains the same as the date set in the Initial Review unless the IACUC chooses to be more

restrictive in the approval period as a result of the change. Any change in this period is noted on the IACUC Master List.

12.3.2.6 All amendments are incorporated into the original protocol during the triennial application.

12.3.3 Designated Member Reviews (DMR) are processed as follows:

12.3.3.1 The Amendment Package, consisting of a completed Amendment Form including description of the amendment, justification for the amendment, species and number requested, justification for the number requested, and the method of anesthesia and/or euthanasia, is submitted by the Principal Investigator to the IACUC Administrator.

12.3.3.2 The IACUC Administrator sends the amendment to the IACUC Chair, Attending Vet and NASA Liaison, if applicable, to determine whether DMR approval is appropriate.

12.3.3.3 If the amendment is deemed appropriate for DMR, it is e-mailed to all IACUC members with a required response date and time (48 hours generally, 24 hours if urgent). If no IACUC member requests full board review and a majority of the members have responded, the amendment is approved by the IACUC Chair using the Designated Member Approval Form.

12.3.3.4. If any member feels the amendment should not be approved by designated member review, the amendment is submitted as part of the next monthly IACUC agenda. The investigator is notified of the reason the protocol will be reviewed by the full board.

12.3.3.5 The approval period remains the same as the date set in the Initial Review unless the IACUC chooses to be more restrictive in the approval period as a result of the change. Any change in this period is noted on the IACUC Master List.

12.3.4 Administrative reviews are processed as follows:

12.3.4.1 A memo or e-mail describing the administrative revision is submitted by the Principal Investigator to the IACUC Administrator.

12.3.4.2 The IACUC Administrator sends the memo or e-mail to the IACUC Chair and Vet to determine whether administrative review and approval is appropriate.

12.3.4.3 If the memo or e-mail is deemed appropriate, the IACUC Chair and Vet may approve it administratively.

12.4 The IACUC Administrator forwards the determination of the IACUC in an approval memo to the Principal Investigator and BLAF Manager, as in the Initial Review.

12.5 If the protocol amendment is approved, the Recap Sheet is revised to include the description of the modification, the date approved and any other information required to be updated.

13.0 CONTINUING REVIEW

13.1 The period for which the protocol has been approved is noted on the Approval Memo and is sent to the Principal Investigator as a condition of the protocol. The information is also recorded on the IACUC Master List. The approval period is determined by the IACUC during a Full Committee Review and shall be for a period of time that shall not exceed one year, but which may be of shorter duration either at the request of the PI or as a result of other concerns arising during protocol review which mandate a shortened approval period. Approval period for addenda shall in no case exceed that of the associated protocol.

13.2 **Assurance of the Annual Review Process**: Procedures to assure that Continuing Reviews are done in a timely manner and that studies are not conducted beyond the approval period are as follows:

- 13.2.1 The IACUC Administrator informs the Principal Investigator of the date by which the IACUC Continuing Review Package must be returned in order to obtain IACUC approval prior to the approval expiration date.
- 13.2.2 The IACUC Administrator is responsible for notifying the IACUC Chair and the PI's Chair when a protocol is in default with regard to Continuing Review.
- 13.2.3 When the IACUC Chair is notified of defaults, he/she shall issue an order in writing to the Principal Investigator to suspend the protocol pending Continuing Review approval by the IACUC. Any animals on the protocol will be transferred to the BLAF holding protocol.
- 13.2.4 Every effort is made to avoid interruption of an otherwise active protocol and to prevent studies from being conducted beyond the approval period. Activities designed to prevent these include:
  - 13.2.4.1 The IACUC Administrator reviews the IACUC Master List and notes all protocols due for Continuing Review and sends a Continuing Review Package to the appropriate Principal Investigators two months in advance of the expiration of the approval period.
  - 13.2.4.2 BNL relies on the integrity of the professional staff to notify the IACUC and to voluntarily discontinue protocols pending Continuing Review. However, BNL can and may decide to sanction staff members who violate policies.

13.3 **Procedures for Continuing Review** are as follows:

- 13.3.1 Prior to the protocol expiration date, the Continuing Review Form is sent to the Principal Investigator for completion.
  - 13.3.1.1 The Continuing Review Form, which must be signed by the Principal Investigator, requests the following information:
    - (i) species and number of animals placed on study;
    - (ii) justification of singly housed animals;

(iii) pain/distress category;
(iv) status of protocol (active, not started, inactive, completed);
(v) personnel working on protocol and years of experience in animal handling;
(vi) a progress report of work done and data collected during the past year or a copy of a progress report provided to funding agencies;
(vii) unanticipated findings, morbidity or mortality involving the animals, the cause(s) if known and how these problems were resolved;
(viii) a literature search for alternatives to use of animals;
(ix) a literature search for alternatives to procedures causing momentary or slight pain or distress to the animal;
(x) a statement that the activities do not duplicate previous experiments;
(xi) a description of future plans.

13.4 The Continuing Review Package is returned to the IACUC Administrator for review.

13.4.1 The IACUC Administrator reviews the package for completeness and updates the Recap Sheet with the information provided.

13.4.2 The IACUC review and approval process for Continuing Review of a protocol is the same as for an Initial Review except that it reviews the Recap Sheet and the progress report presented by the PI.

13.4.3 The new approval period is determined by the IACUC.

13.5 The IACUC Administrator forwards decision memos to the Principal Investigator and BLAF Manager, ESR Coordinator and Facility Manager as in an Initial Review.

13.5.1 If an investigator does not respond to a Modifications Required memo within one month, the investigator will be sent a memo requesting they suspend work under the protocol until the conditions have been met. A copy of the memo will be sent to the investigator's Department Chair.

13.5.2 If the investigator does not voluntarily suspend the protocol, the IACUC will suspend the protocol and report such suspension to the IO with a recommendation that the suspension be reported to OLAW.

13.6 Compliance Monitoring

Post-approval compliance monitoring is handled by the following:

13.6.1 Daily observation of animals by trained animal care personnel and communication to the veterinary staff for follow-up;

13.6.2 Post-operative care by trained personnel;

13.6.3 During the semi-annual inspection, IACUC members compare work being performed in an animal laboratory with procedures approved in the IACUC protocol and check that personnel have taken required training.

13.6.4 The IACUC or a subgroup of the IACUC may periodically arrange for the observation of research being carried out under a protocol. These observations serve to: educate the IACUC on routine procedures within a protocol; and to ensure that research is being carried out as prescribed within a protocol.

14.0 PROCEDURES TO BEGIN AN APPROVED PROTOCOL

14.1 Following approval, the IACUC Administrator enters the protocol and associated information into the IACUC Master List. A copy of this list posted on the IACUC SharePoint site.

14.2 When a Principal Investigator wants to schedule a study, s/he contacts the BLAF Manager.

14.3 Before the study starts, the BLAF Manager:

- 14.3.1 Checks with the IACUC Master List that the protocol has been approved;
- 14.3.2 Verifies through the IACUC Master List that the correct species of animal is being used;
- 14.3.3 Verifies that at the time scheduled for work to begin, the BLAF is properly equipped and staffed to handle the work.

15.0 PROCEDURES TO SUSPEND, INACTIVATE OR TERMINATE A PROTOCOL

15.1 The IACUC has the authority and responsibility to suspend, inactivate and/or terminate any protocol at any time that it feels such action is warranted. A Principal Investigator may also voluntarily inactivate or terminate a protocol.

15.2 **Voluntary Process**:

15.2.1 The Principal Investigator notifies the IACUC Administrator of his/her decision to inactivate or terminate a protocol by submitting a memo.

15.2.2 The Principal Investigator has the responsibility to report to the IACUC Chair any unanticipated events and to voluntarily interrupt the protocol until appropriate changes in the protocol can be approved by the IACUC.

15.2.3 The IACUC Administrator then notifies the IACUC and the BLAF Manager in writing of these actions.

15.2.4 Any animals on the protocol are transferred to the BLAF Holding Protocol.

15.3 **Involuntary Process**:

15.3.1 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 Guide, the Institution's Assurance, or IV.C.1.a.-g. of the PHS Policy.

15.3.2 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.

15.3.3 Following the IACUC decision to suspend a protocol, the IACUC Administrator shall notify the Principal Investigator, BLAF Manager, Institutional Official and the Principal Investigator’s Department Chair of the suspension.

15.3.4 The IACUC Administrator sends a letter signed by the Institutional Official to OLAW, with a copy to AAALAC, to report the suspension.

15.3.5 The Principal Investigator notifies the sponsor of the research of the action.

15.3.6 Any animals on the protocol are transferred to the BLAF Holding Protocol.

16.0 RECEIVING AND HANDLING ALLEGATIONS OF MISTREATMENT OR PROTOCOL NONCOMPLIANCE

16.1 Reports of concerns involving the care and use of animals are submitted in writing or verbally to the Institutional Official, IACUC Chair, IACUC Administrator and/or Attending Veterinarian. Reports may be submitted anonymously by phone or in writing.

16.2 The allegation is forwarded to the IACUC Administrator.

16.3 The IACUC Administrator ensures the IO, the IACUC Chair and the AV are notified of the allegation.

16.3.1 The IACUC Chair, or a designee, will investigate the allegation as soon as possible to determine the immediate health and wellbeing of the animals are adequately addressed.

16.3.2 The IACUC Chair will refer allegations related to biological, chemical, or radiological safety to the appropriate BNL office to determine if the health and wellbeing of humans are adequately addressed.

16.3.3 Deficiencies compromising the immediate health and welfare of the animals will be remedied immediately by the Attending Veterinarian or designate and deficiencies compromising the immediate health and wellbeing of the humans will be remedied immediately by the appropriate BNL official.

16.4 The IACUC Chair or designee will thoroughly investigate all aspects of the allegation and prepare a written incident report. The incident report will be submitted to the IACUC for review and discussion.

16.4.1 Should the findings of the investigation indicate that the allegations were invalid; the incident report shall outline the findings leading to such conclusion.

16.4.2 Should the findings of the investigation suggest that the allegations have substantial validity; the incident report shall outline the findings leading to such conclusion.

16.5 The IACUC Chair will send a copy of the incident report and a memo outlining the alleged mistreatment or noncompliance issues to the Principal Investigators involved inviting them to appear at an IACUC meeting if the investigation supported the validity of the allegations. The objectives of the meeting are to:

16.5.1 Review the incident report and discuss the allegations with the investigator(s) involved

16.5.2 Substantiate the validity/invalidity of the allegation by a majority opinion of the IACUC using NIH Guidance on Reporting dated 02/24/05.

16.5.3 Record a listing of noncompliance issues

16.5.4 Record all minority opinions of the noncompliance issues
16.5.5 Record a listing of recommended corrective actions/sanctions for the investigator
16.5.6 Record all minority opinions of the recommended corrective actions/sanctions
16.5.7 Decide on the response to the originator of the allegation

16.6 The IACUC Chair will send a memo to the Institutional Official (IO) delineating the noncompliance issues and the recommended corrective actions/sanctions. The Institutional Official, in consultation with the IACUC Chair and Attending Veterinarian, may impose further corrective actions/sanctions for the investigator or support the IACUC's recommended corrective actions/sanctions.

16.7 The IACUC Administrator will send a letter to the investigator describing the noncompliance issues and the required corrective actions/sanctions, with related deadlines, prescribed by the IACUC. The letter will also inform the investigator of his/her option to appeal the decision by providing to the IACUC Chair, within a specified number of days of receipt of the letter a memorandum detailing the basis of the appeal and requesting a second meeting with the IACUC.

16.8 The IACUC Chair will also inform the originator of the allegation, if necessary, of the IACUC's disposition of the allegation.

17.0 DETERMINATION OF CORRECTIVE ACTIONS/SANCTIONS

17.1 All allegations reported to the BNL IACUC shall be submitted for review by the IACUC as described above. If the IACUC, by majority vote, finds the allegations have merit and represent noncompliance, the following guidelines are to be used to determine corrective actions/sanctions:

17.2 For Serious or Continuous Noncompliance Issues

17.2.1 Acts of noncompliance are deemed serious if they can or do affect the health, safety or wellbeing of animals or personnel or represent continuing noncompliance with Federal or BNL policies. Examples of serious issues would be the failure of animal care and use personnel to adhere to IACUC - reviewed and approved institutional policies and procedures or a serious deviation from the provisions of the Guide.

17.2.2 If the IACUC determines the reported problem is serious, it may, in consideration of the nature of the research study and the reported problem, institute one or more of the following sanctions:

17.2.2.1 Terminate IACUC approval of the respective research study

17.2.2.2 Suspend IACUC approval of the respective research study pending completion and acceptance by the IACUC of a written plan for the correction and /or prevention of the problem

17.2.2.3 Suspend further animal orders for the research study pending completion and acceptance by the IACUC of a written plan for the correction and/or prevention of the problem

17.2.2.4 Institute an IACUC-mandated corrective action plan

17.2.2.5 Take such other action as the IACUC deems appropriate

17.3 Minor Noncompliance Issues

17.3.1 Acts of noncompliance are deemed minor if they do not affect the health, safety or wellbeing of animals or do not represent continuing or willful noncompliance with Federal or BNL policies. If the IACUC determines that the reported problem is minor, it may, in consideration of the nature of the research study and the reported problem take one or more of the following actions:

17.3.1.1 Elect to make corrective action only

17.3.1.2 Provide a verbal and/or written listing of the issue of noncompliance to the investigator and require a corrective action plan at a regular meeting of the IACUC and recording this incident in the IACUC minutes

17.3.1.3 Provide a written listing of the issue of noncompliance to the investigator and require a corrective action plan within a specified time period. The letter may or may not

be copied to the investigator's department chair depending on the IACUC's decision on the sanction.

17.4 **Reporting**

17.4.1 All suspensions will be reported to OLAW, USDA (if applicable), AAALAC, the PI's funding agency and the PI's home institution, if not BNL, BHSO and QMO.

17.4.2 All serious or continuing noncompliance issues and their resolution will be reported to OLAW and the agency funding the study.

18.0 SEMI-ANNUAL REVIEW OF PROGRAM AND FACILITIES

18.1 Every six months, the IACUC reviews the Program for Animal Care and Use and the Brookhaven Laboratory Animal Facilities (BLAF).

18.2 A copy of the Program is reviewed by the IACUC using the "Semi-Annual Program Review Checklist" from Office of Laboratory Animal Welfare (OLAW). Individual members are assigned sections of the Program on a rotating basis.

18.3 All SOPs that may impact animal welfare, including the Disaster Plan are reviewed at least every three years or if they undergo a major revision.

18.4 Any comments or changes recommended and approved by the IACUC are made to the Program following the meeting at which the Program was reviewed.

18.5 The BLAF in Building 490 is inspected by the IACUC, including government vehicles used for animal transport. The inspection is conducted using the "Facility Inspection Checklist" from OLAW. Previous findings are reviewed to determine if there are ongoing findings.

18.6 A subcommittee of the IACUC consisting of at least two members shall inspect the laboratories where experiments involving animals are conducted. During a disaster, a qualified individual who is not an IACUC member may be authorized to perform the inspection. If no active studies are being performed during the semi-annual inspection, arrangements will be made to observe active studies during periods other than the semi-annual inspection.

18.7 Two protocols are selected and required training for personnel listed on the protocol is checked in the BNL database and the Experimental Safety Review (ESR) is compared to the protocol to ensure it contains the same information as the ESR.

18.8 A Semi-Annual Report draft is prepared by the IACUC Administrator based on findings from the inspections. Findings must be corrected by the required date and noted in the report. 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. The Semi-Annual Report includes any other information about which the IACUC wants to apprise the Institutional Official, including the animal census for the previous six (6) months. Any IACUC-approved departures from the PHS Policy and the Guide and reason for each departure are also included. If there are no departures, that will be stated in the report. No member will be involuntarily excluded from participating in any portion of the reviews. All minority views are included in the report. The IACUC Administrator will gather information from other sources, such as User Satisfaction and End of Run reports from the NASA Liaison, and compile a list of all reports sent to oversight organizations and all IACUC actions during the reporting period.

18.9 The Semi-Annual Report is reviewed and approved by the IACUC at the next IACUC meeting. All IACUC members present sign the attached signature page.

18.10 The Semi-Annual Report is sent to the Institutional Official.

9.0 MISCELLANEOUS IACUC POLICIES PERTAINING TO ANIMAL RESEARCH

19.1 No animals may be removed from the BLAF and maintained outside of the BLAF for more than 24 hours. Requests for exceptions to this rule due to extenuating circumstances may be reviewed and approved by the BLAF Manager for periods less than one week. Housing over one week must be reviewed and approved by the full IACUC.

19.2 The IACUC will decide for each protocol, based on risk assessment and risk reduction, the necessity of continuously monitoring animals undergoing experimental procedures. The IACUC shall require a detailed description of how the risk will be minimized (through monitoring, design of apparatus, etc.). The research group must always monitor animals under anesthesia until they have recovered.

19.3 Animals transported through public areas must be in microisolator or filter top cages.

19.4 Ketamine/xylazine mixtures must comply with Pharmacy policy and may be maintained for a maximum of 28 days.

19.5 Rodents less than three weeks old must be received with their dams. Amendment not required to change rodent ages.

Lab	Type of Agreement	Proposal Number	Sponsor Name	Type of Animal	Approximate # of Animals Involved	Project Title	Brief SOW

SC INSTITUTIONAL REVIEW: NON-DOE FUNDED WORK PROPOSAL INVOLVING ANIMAL USE

1) Site Office and Lab Name:

2) Agreement Mechanism: □ IAG □ Non-Fed SPP □ CRADA □ ACT □ Other (specify)
□ User Facility Agreement

3) Agency/Sponsor Name, Address and Point of Contact:

4) Proposal Number and Title:

5) Principal Investigator/Project Leader Name and Phone Number:

6) Period of Performance (POP):

7) Total Estimated Project Cost: ($M):_____ Cost by FY: FY17,_____

8) Identification of animal(s) subject to use in proposed work:

Larger Mammals (specify) _____

9) Summary statement of work (SOW) (may attach detailed statement of work):

10) Laboratory as R&D performer - specify why the laboratory is the only performer who can conduct/perform the sponsored research.

11) Benefit to Government/SC/SC Labs:

12) Is work being conducted in accordance with an active Agency to Agency MOA/MOU?
□ Yes –attach copy to worksheet

13) Decision **[for mammals only]**: □ SC-1 Concur
□ SC-1 Non-concur
_____Date