Institutional Animal Care and Use Committee Standards

Contents

1 Institutional Animal Care and Use Committee (IACUC) 2

2 Protocol Submission 8

3 Triennial Reviews 9

4 Who May Serve as an Investigator 10

5 Conflict of Interest 12

6 Retention of Research Records 12

7 Investigator Training Requirements 12

8 Occupational Health and Safety Program 14

9 Personal Protective Equipment (PPE) 15

10 Animal Transportation 15

11 Congruency Review 15

12 Interinstitutional Agreement 15

13 Collaborating Organizations 16

14 Monitoring 16

15 Semi-annual Inspections 17

16 Reporting Requirements 18

17 Animal Welfare Concerns 21

18 Use of Animal Tissues 24

19 Projects Using Recombinant DNA or Infectious Agents 25

APHIS
https://www.aphis.usda.gov/awa/research-facility-report/annual-summary

1 Institutional Animal Care and Use Committee (IACUC)

1.1 Policy

In accordance with the Animal Welfare Act of 1966 and the Health Research Extension Act of 1985, the State University of New York at Stony Brook fosters a research environment that promotes the respect for the welfare and safety of animals used in research. All use of vertebrate animals in research, teaching and testing is regulated by the Institutional Animal Care and Use Committee (IACUC). Animal welfare and IACUC policies apply to all faculty, staff, students, and visitors. This includes both research and teaching activities that are:

- Sponsored by Stony Brook University
- Conducted by Stony Brook University researchers
- Taught by Stony Brook University faculty
- Conducted using Stony Brook University property or facilities

1.2 Mission

The mission of the IACUC is to:

- Protect animals, employees, staff, students, and the public involving the use of animals in research
- Perform required reviews for the use of animals in research with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society

1.3 Organization and Operation

The IACUC is administered by the Office of Research Compliance (ORC), which also monitors compliance and promulgates policies and procedures to ensure that the IACUC membership is duly constituted in accordance with federal regulations.

The regulations require a minimum of 5 members on the IACUC. The Stony Brook IACUC has approximately 14 members representing various areas of expertise. The IACUC chair is selected from the IACUC members by the Vice President for Research. The IACUC reviews the minutes and reports.

Applications (i.e., Curriculum Vitae) for new members are submitted to the IACUC Coordinator and brought to the IACUC meeting for review. The IACUC members determine if the individual meets the requirements for membership on the committee. Once the review of the CV is complete, the individual is notified regarding their status as a potential IACUC member. Following IACUC member training (CITIProgram.org) and in-person training (Office of Research

Compliance) the potential new member signs a confidentiality agreement and may then observe an IACUC meeting.

Changes in membership and applications for new members must be submitted as soon as vacancies occur on the committee. A current curriculum vitae for each committee member must be received by the IACUC Coordinator every two years.

The IACUC meets at least once per month, or more frequently, at the discretion of the IACUC Chair. The agenda, time and location of the meeting and meeting materials are available in advance to all IACUC members. Members who do not attend at least 50% of meetings in a calendar year may be dropped from membership.

Meetings require a quorum to occur (more than 50% of the members). Protocols that involve special populations such as wildlife, should be reviewed by a specialist with expertise in that area or a consultant. The IACUC members vote on each protocol reviewed at the meeting. A majority of the members must vote to approve the application for the application to be approved. A member who has any involvement in a protocol or some other conflict of interest must abstain from voting on it.

Members are under strict requirements to maintain confidentiality regarding service on the IACUC. This requirement remains in full force during the entire term of service with the IACUC and continues in effect after such affiliation terminates.

Decisions of the committee are documented in the minutes. Minutes are confidential documents. Access is available to IACUC members at all times. The minutes are drafted by the IACUC Coordinator. The minutes include a list of the members who were present for the meeting, voting results and outcome of review. The minutes include the numerical results of votes on protocols. Comments from the protocol reviews are communicated to the Principal Investigator by the IACUC Coordinator.

It is the responsibility of the Principal Investigators to report all adverse events related to their protocols. If the IACUC receives an adverse event report, the IACUC will review the adverse event at a convened meeting. If it is determined that the adverse event is serious, the IACUC has the responsibility for reporting the event to the regulatory agencies.

The following are functions of the IACUC according to the Animal Welfare Act, Guide for the Care and Use of Agricultural Animals in Agricultural Research and Training and the Public Health Service Policy on Humane Care and Use of Laboratory Animals.

- Review and approval of protocols, or changes in protocols, involving the care and use of animals in research or teaching activities
- Suspension of an animal care and use activity that fails to comply with federal regulation or an IACUC approved protocol

- Inspections of all SBU animal housing facilities and animal use areas (including off-site areas), using specified standards as the basis for evaluation and reporting
- Review of SBUs program for the care and use of animals, using specified standards as the basis for evaluation and reporting
- Make recommendations to the IO regarding any aspect of SBU's animal facilities or program
- Review concerns involving the care and use of animals at SBU

At a minimum the Committee consists of not less than five regular voting members, and at a minimum it includes representation from each of the following:

- Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the institution;
- Scientist experienced in research involving animals;
- Nonscientific member (for example, ethicist, lawyer, member of clergy); and
- A member non-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.

All reviews, initial, continuing review and modifications are completed electronically by the IACUC members. While optimal, there is no requirement to conduct the IACUC meetings in-person.

Members receive notification from myResearch IACUC about upcoming studies. The agenda is available to members the day of the meeting. Members have continual access to all meeting materials through the electronic submission and review system. New protocols, amendments and triennial reviews as well as concerns and other business requiring full committee action are placed on the agenda for discussion. Members use a sign in and password to log in to myResearch IACUC.

Two reviewers are assigned by the IACUC Coordinator. More reviewers may be assigned at the Chair's discretion. The reviewers include members of the Committee and are responsible for presenting a summary of the protocol at the meeting along with any concerns or points requiring clarification. The reviewer can discuss their questions with the investigator prior to bringing the protocol before the full IACUC. The secondary reviewer adds any additional concerns. Comments from the veterinarian are added. The protocol is then open for discussion by the full Committee. Each member has the opportunity to read and review the protocol prior to the meeting, and then a vote is taken. All members' votes are recorded in the minutes of the meeting. An approval letter or letter asking for further clarification will be sent to the PI.

The Committee may, at its discretion, obtain consultation from individuals with expertise in specialized areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IACUC. The IACUC shall consult with General Counsel and other

University Officials, as indicated, to address issues pertaining to institutional policies, applicable law, and standards of conduct and practice. These individuals do not vote. Regular members of the IACUC do not receive monetary compensation.

The IACUC must receive sufficient information regarding proposed activities to make the determinations as required by regulations. The IACUC Coordinator will conduct a pre-review of submitted materials. A new protocol or amendment will not be added to a meeting agenda until this review is complete. If the submission is incomplete or lacks information necessary to conduct a review, it will not be reviewed until the information is provided.

Proposed activities must be reviewed in accordance with USDA regulations and PHS policy. The following should be used to ensure that the federal requirements for granting IACUC approval are met:

- **Methods**
  - The importance of the study to human or animal health, the advancement of knowledge, or the good of society
  - Attention to the 3Rs – replacement, reduction and refinement
  - Identification of the species and the approximate number of animals for each species;
  - A rationale for the appropriateness of the species;
  - A complete description of the proposed use of the animals and/or any reuse; and
- **Duplication** -- Assurance that activities do not unnecessarily duplicate previous efforts must be provided. Exceptions for this are activities and protocols that are performed for educational or training purposes.
- **Animal numbers** – The IACUC requires that the experimental design be described and estimated animal numbers justified either with a power calculation or a reference to previously-published work of comparable scientific design.
- **Alternatives** – In the case of any protocol which entails more than momentary pain or distress to the animals, the investigator must perform a literature review seeking alternatives which could achieve the same scientific objectives with a lesser degree of pain/distress. The investigator must describe in a narrative what leads him/her to the conclusion that there are no alternatives to the proposed procedures.
- **Housing/Health** -- Animal living conditions must be consistent with standards of housing, feeding and care directed by veterinarian or scientist with appropriate expertise. Social housing is expected, depending on the species and the circumstances surrounding the research procedures. Medical care must be provided by a qualified veterinarian. Single housing of social species must be scientifically justified. Lack of bedding must be scientifically justified.
- **Procedures** -- A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals. Withholding of analgesics must be scientifically justified.

- **Genetically Modified Animals** -- All novel GMAs must be monitored in the F1 generation for the development of unexpected phenotypes. All unexpected phenotypes that affect the health and well-being of the animal are considered a reportable event and must be reported to both the DLAR and the IACUC by submitting an amendment to myResearch IACUC. If unexpected phenotypes are identified, then additional monitoring and analysis may be warranted as determined by a Stony Brook University veterinarian or requested by the IACUC. Stony Brook University veterinarians must be consulted by the research team to identify means of alleviating any pain or distress associated with the phenotype. Phenotypes that are highly recurrent within a given line must be described in the protocol to avoid the necessity of continued reporting. Once the modification is approved, the phenotypic condition will not be subject to further reporting as it is no longer unexpected.
- **Restraint** -- When restraint is proposed in an animal use protocol, the protocol must include a description of the restraint device, the duration the animal will be restrained, and a description of how the animal will be acclimated, trained prior to the procedure, and observed. It must also include what signs and/or behaviors will indicate that the animal should be removed from the restraint and/or study. Use of prolonged restraint must be scientifically justified.
- **Food and Fluid Regulation** -- Food and/or fluid regulation must be scientifically justified based on the scientific objectives of the study. The least amount of restriction that will achieve the objectives must be used.
- **Pain and Distress** -- A concise description of efforts to mitigate animal pain and distress must be provided. For protocols which entail more than momentary pain/distress without provision of analgesia, a specific scientific justification for withholding analgesia is required.
    - If an animal or group of animals undergoes any type of procedure, the lowest category to which the animal or group of animals may be assigned is Category C. An animal or group of animals must be assigned to the highest pain and distress category that will apply to the animal(s) at any time while the animal is associated with the IACUC protocol, regardless of the duration of time the animal(s) is on the protocol.
- **Surgery** -- Requirements for sterile surgery and pre/postoperative care must be met. An animal may not be used for several major operative procedures from which it will recover, without meeting specified conditions. Scientific justification must be provided for multiple survival surgeries. If the investigator plans to perform multiple survival surgeries on USDA regulated species, in separate unrelated protocols, APHIS approval needs to be received and included in the application. For non-survival surgery, the hair is clipped gloves are worn and instruments and areas are clean. Post-operative monitoring and care are provided by trained personnel and documented.
- **Record Keeping** -- Record keeping is an essential component of peri- and post-operative care. For all surgical procedures, an intra-operative anesthetic record must be kept and included with the surgeon's report as part of the animal's records. In addition to the above requirements, the record should include all drugs administered to the animal, noting the dose, time, and route of administration. The record needs to also include post-operative monitoring and drug administration.

- **Drugs** - The use of expired drugs, medical supplies and/or devices is not acceptable practice~~,~~ as it may result in harm to an animal and ~~may~~ compromise the integrity of research data. Principal Investigators (PIs) and laboratory staff are responsible for ensuring that expired Drugs, Medical Supplies and/or Devices are properly disposed of by their expiration date.
- **Alternatives** –

1. Develop a comprehensive list of keywords.
   a. Consider non-animal models that may be available, such as computer simulations or *In vitro* cultures. Search terms may include "alternative," "simulation," "model" and "in vitro."
   b. Consider the potential application of phylogenetically lower animal models, such as invertebrates. Justify why they cannot be used for the proposed studies.
   c. Add keyword search terms pertaining to the specific research objectives, any procedures listed as Category D or E, particular techniques, drugs, anesthesia and analgesia, species and strain of animal, and 'endpoints.'
      i. Use synonyms, acronyms and alternative spelling to increase the number of search results. The MeSH function in Pubmed will help find the medical subject heading and any subheadings, allow restriction or explosion of the heading, and help build searches.
      ii. Use of the terms "severity" or "assessment" in the search string may help find refinements or humane endpoints.
   d. A search of each painful or distressful (category D or E) procedure should include at least one of the following appropriate search terms: "refine" or "refinement," "analgesia," "alternative," "pain," "distress," "humane endpoints."

2. Combine keywords into brief search strings.
   a. Keep strings brief to maximize search results or 'hits.'
      i. For example: when considering search strings for refinements (non-painful or less painful alternatives to painful/distressful procedures) to a mouse cecal ligation and puncture procedure, one might include:
         - cecal ligation and puncture model pain severity
         - cecal ligation and puncture animal pain assessment
         - cecal ligation and puncture analgesia
      ii. Further examples of search strings looking for replacement and reduction (alternatives to the species used) could include:
         - peritonitis simulation
         - septic peritonitis in vitro
         - peritonitis sample size
         - ("Peritonitis"[MeSH]) AND ("Animal Use Alternatives"[MeSH])
         - peritonitis AND ("birds" OR "reptiles" OR "amphibians" OR "fish")
   b. If searches result in excessive 'hits,' consider adding or combining terms to help narrow the search.
   c. Develop separate search strings for each potentially painful/distressful procedure.

3. Select databases based on the research area. Commonly used databases include PubMed, Biological Abstracts, PsychInfo, Agricola, Web of Science, TOXNET, Scopus, and BIOSIS. Some laboratory animal and welfare focused journals and magazines can also be useful resources: Altex, Lab Animal, JAALAS, JAAWS. Search engines may also be used as a resource (i.e., Google Scholar), but a minimum of two different databases is required.

4. Search the strings in the databases. Be sure to record the database, search string, date searched, and dates the search covered. Most databases allow searches to be saved by creating an account, for example, "My NCBI" in PubMed.

5. Review any relevant papers that are found; 'Materials and methods' sections of papers are especially important to review for alternatives.

6. Determine whether the search findings can be incorporated into the research plan and related IACUC protocol application.

7. Briefly describe the search and its outcome; this should be done in a narrative format (e.g., paragraph). If no relevant information was found, state this.

2 Protocol Submission

2.1 Initial Protocol Submission

The Stony Brook University IACUC accepts the model of a protocol that has more than one sponsor. The decision on whether to combine protocols is left to the researcher. However, any protocols including USDA species or those projects that are Department of Defense (DOD) funded are required to be submitted as **separate distinct protocols**.

During the development of a protocol, PIs must review the standard library and use already created standard procedures and substances if they are available. The majority of standard substances or procedures require customization to reflect the exact protocol used by the PI. In these cases, the PI must make a copy of the standard and edit it as appropriate. Standards will require review at the time of protocol submission.

It is highly recommended that the veterinarian and the Principal investigator meet prior to the submission of the protocol for a veterinary consult. A veterinary consult is **required** for USDA-regulated species involved in procedures with the **potential for pain and/or distress**.

A procedure or substance may be added to the standard library after it has been reviewed and approved by the IACUC. Expert members of the IACUC committee along with the IACUC Coordinator and the University veterinarian develop the appropriate procedures and substances and the IACUC Coordinator uploads then in myResearch IACUC. They are then reviewed by the IACUC at a convened meeting.

The following should be considered when submitting in myResearch IACUC:

- **Euthanasia/Humane Endpoints** -- A description of any euthanasia method to be used must be included in the protocol. The euthanasia method must be consistent with the recommendations of the current AVMA Panel on Euthanasia (2020 edition or later). Humane endpoints must be established, particularly for studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure, or models of cardiovascular shock.
- **Exceptions and Departures from Requirements** – A written scientific reason must be included.
- **Training** -- Personnel conducting procedures on the species being maintained or studied must have the relevant basic credentials/qualifications and, with requisite assigned training, are appropriate for the assigned work.
- **Congruency** -- The IACUC protocol must align with the grant application (if applicable) that will support animal studies. Differences between the IACUC protocol and the grant application must be addressed and reconciled.

2.2 Amendment to an Approved Protocol

Modifications/amendments to approved protocols must be documented appropriately, reviewed, and approved. An amendment form is completed requesting the modification including an explanation of the changes along with the rationale for the changes. The PI must complete an amendment form in myResearch IACUC, revise the application, and submit it to the IACUC for review and approval. The IACUC Coordinator and IACUC Chair will determine if the modification is "minor" or "significant". Significant modifications include changes that have, or have the potential to have, a negative impact on animal welfare (e.g., change from survival to non-survival surgery, changes resulting in greater pain, distress or degree of invasiveness). A minor modification can include, addition of food or water restrictions, an increase in animal numbers, or a change in reagents, anesthetics or analgesics, sedation or experimental substances. A minor modification is reviewed through Designated Member Review (DMR), whereas a significant modification needs to be reviewed by the full committee.

Modifications that can be performed administratively include corrections of typographical errors, correction of grammar, contact information updates, or removal or addition of personnel (other than the PI).

NOTE: When a grant is funded, an amendment to the existing protocol should be submitted to add the grant information as well as any new animal work from the approved grant.

3 Triennial Reviews

All protocols are reviewed on a triennial basis. A progress report over the previous approval period is required. Triennial reviews are comprehensive, de novo reviews. The Committee may

require that the research be restricted, modified, reviewed more frequently, or terminated/suspended. Alternatively, special precautions or Committee-imposed restrictions, or shortened review periods, may be modified if current data support such actions. Protocols covered by the Animal Welfare Act (USDA-covered species) no longer require an annual continuing review.

3.1 Amendments at the Time of Triennial Review

Often, as part of the completion of the triennial review, it becomes apparent that an increase in animal numbers will need to be made. If Investigators need to make a change in the currently approved protocol, they must submit a separate amendment request through myResearch IACUC. The same reviewer will be assigned the triennial review and any associated amendments whenever possible.

Approval
Approval will be provided by a letter sent to the PI stating that the study is approved. The approval letter will indicate an expiration date which can only be extended through the Continuing Review process.

Expired Approvals
Extensions beyond the expiration date cannot be granted. The electronic system will automatically place the protocol in a lapsed state when the expiration date has passed. Once expired, research activities are suspended and animals are moved to an institutional holding protocol, pending continued approval of the research by the Committee. Researchers found to be conducting research activities without a current IACUC approval are in noncompliance with the regulations, and the activities will be reported to the relevant funding agencies.

Closures
In the event that the entire protocol is closed, notification must be done by closing the research in myResearch IACUC using “request closure.” Closure of the study is done administratively. All animals use on a specified protocol is stopped and no further purchase of animals can be made under the specified protocol number.

4 Who May Serve as an Investigator

Eligibility requirements for conducting vertebrate animal research vary depending on the role of the researcher. Research personnel must be appropriately qualified by training and/or experience to perform their research responsibilities.

Principle investigator (PI)
The PI is ultimately responsible for assuring compliance with University IACUC policies and procedures and Animal Welfare regulations. The PI must have a faculty appointment. Although

the PI may delegate tasks to members of his/her research team, s/he retains the ultimate responsibility for the conduct of the study.

Because PI responsibilities involve direct interaction and supervision of the research team, the PI must be a current employee of the University who is operating within their University role to oversee the conduct of the study. PIs leaving the institution are responsible for notifying the IACUC well in advance of their departure to discuss closure or transfer to another PI.

The PI must provide members of the research team with sufficient oversight, training and information to facilitate appropriate procedures and protocol adherence. The PI is expected to be knowledgeable about and comply with the requirements of the following:

- The Guide for the Care and Use of Laboratory Animals (PDF);
- The Animal Welfare Act;
- IACUC Policies and Procedures; and
- The terms and conditions of any research agreements (with government or private sponsors -- NSF and DOD may have specific requirements).

If a PI is unable to fulfill his/her responsibilities, the PI must either designate a person to be in charge and fulfill all responsibilities for oversight of the protocol in their absence or provide a plan for coverage (one option is to cease activities during an absence – this requires IACUC notification). If a formal leave is planned (e.g., sabbatical, medical, family or other official leave), the IACUC needs to be notified, so that it may redirect protocol inquiries during that time. The responsible designee must understand the protocol and comply with the requirements.

Students

A member of the study team can include, but is not limited to, any of the following: fellow, resident, post-doctoral trainee, and any student (graduate or undergraduate).

Students cannot conduct animal research without having a faculty sponsor who will be the PI of record and who will be institutionally accountable for overseeing the conduct of the research activities. The faculty sponsor must be employed by the institution.

Key Personnel

Key personnel are individuals employed by the University who contribute to the scientific development or execution of a project, whether or not they receive salary or compensation under the protocol. This includes any individual conducting experiments. Key personnel must complete the required training, have a stony Brook University email address, and be listed as a member of the study team. Key personnel are expected to be knowledgeable about and comply with the requirements of the following:

- The Guide for the Care and Use of Laboratory Animals (PDF);
- The Animal Welfare Act; and
- IACUC Policies and Procedures

5 Conflict of Interest

As an academic research institution, SBU must continually dedicate itself to the integrity of the research enterprise. Conflicts are not inherently wrong, and as long as they are disclosed and appropriately managed or resolved, they do not distort and/or can benefit the research process. A conflict of interest may arise when a faculty or staff member has a relationship with an outside organization that puts the faculty or staff member in a position to influence the university's decisions in ways that could lead directly or indirectly to financial gain for the faculty or staff member or his or her family or give improper advantage to others to the detriment of the University. Disclosures are done through the myResearch software.

6 Retention of Research Records

The regulatory mandated duration for records retention varies depending on which regulations apply to the research in question. SBU investigators need to ensure that their plan for record retention complies with the federal regulations as well as Stony Brook University records retention policy.

- IACUC records are all records of communication with the IACUC and all approval documents. myResearch IACUC retains all of these documents within the electronic system.
- Research records refer to documentation of all observations and other data pertinent to the investigation. Responsibility to keep these records falls to the PI.

7 Investigator Training Requirements

7.1 General Training

A web-based training program, Collaborative Institutional Training Initiative (CITI), is used to provide general training. All PIs and key personnel must take the “General Lab Animal Training – Basic Course” through CITI in addition to the species-specific course for each species that is listed on the protocol before they will be added to the roster. CITI training courses are required to be completed **every three years**.

7.2 General Lab Animal Course

IACUC procedures, the principles of the Three R’s, methods for minimizing animal pain and distress, facility access and logistics, use of PPE, basic animal observation and restraint, reporting animal welfare concerns, surgery/anesthesia, euthanasia, blood collection, social housing etc., are all to be included in the general mandatory course.

7.3 Species-Specific Course(s)

Species-specific course(s) must be taken for each species described in the approved protocol. Courses available include; mouse, rat, amphibians, guinea pigs, rabbits, cattle, horses, and swine.

7.4 Documentation

Documentation of completion will appear on the CITIProgram.org website. The Office of Research Compliance has created a training resource and FAQ webpage which includes a link to the CITI Program training.

7.5 Animal Care Staff Training

Training of animal care staff includes review of relevant SOPs, one-on-one training by the Facility Manager, and "shadowing" of more experienced personnel. In addition, all of the animal care staff review the IACUC and the risk management and safety on-line training. Other opportunities for training include staff and animal user meetings and seminars.

7.6 Hands-On and CITI Training for Study Personnel

“Hands-on” training for present and incoming study personnel is provided by the veterinary staff. Regularly scheduled small group sessions cover restraint, injection and blood sampling techniques, recognition of common health problems, aseptic technique, anesthesia and euthanasia. This training is offered to individuals on an as-needed basis following consultation with the University veterinarian.

CITI training courses are required to be completed **every three years**. Reminders letters sent from the CITI electronic system will be sent to personnel as their training expiration date nears.

7.7 Other Training

Biohazardous Agents Training
PIs that utilize hazardous agents will train those study members who will be handling the agents. Assistance may be requested from SBU’s Biosafety Officer.

Chemical Safety Training
Stony Brook University’s Environmental Health & Safety Office (EHS) offers Chemical Safety Training that covers general laboratory safety, an overview of regulations, OSHA laboratory standards and the Chemical Hygiene plan. Chemical labeling and storage requirements are available on the EHS website.

Radiation Safety Training

Radiation Safety training is a requirement of Stony Brooks NYS Radioactive Materials License. Training is required before first use and annually thereafter. Contact radiation safety to be assigned training and ensure that there is an affiliated with an internal radioactive use permit. Successful completion of a training quiz is required at the completion of the course.

https://ehs.stonybrook.edu/commcms/environmental-health-and-safety/services/training/index.php for a link to the radiation safety training.

Animal Care Staff and Biohazards

All animal caretakers are instructed and trained by the DLAR Manager in the husbandry, sanitation procedures and precautions to be followed when working in any biohazard area. Each protocol utilizing hazardous agents requires an instruction sheet which is reviewed by the Manager with the caretaker and is posted on the animal room door. The instructions on the sheet include animal and personnel safety.

Other Training Resources

Webinars, guest speakers and/or consultation on various relevant topics such as animal research and mouse colony management are provided to the research community.

Information on the following topics is also available: Levels of discomfort/distress in animal experimentation; anesthetic and analgesic drug formulary for different species; AVMA Guidelines for Euthanasia.

Self-study materials on handling and basic manipulative procedures for commonly used laboratory animals are also available.

8 Occupational Health and Safety Program

Each institution maintains an occupational health and safety program as an essential part of the overall animal care and use program. The occupational health and safety program is consistent with federal, state, and local regulations and should focus on maintaining a safe and healthy workplace**. All individuals who have contact with animals (including those individuals working in the field) must have occupational health clearance.** Depending on the facility, research activities, hazards, and animal species involved, the program may not affect all personnel equally. The Clinical Preventive Medicine Program oversees the University's occupational health and safety program. The website can be consulted for more information.
https://ndlar-graph.azurewebsites.net/

9 Personal Protective Equipment (PPE)

PPE appropriate to the room is indicated by signage on the door and discarded in the room prior to exiting the area only for the current hazard rooms. PPE is provided by the animal facility for use by research personnel as well as animal care staff. This PPE may include gowns and masks, gloves, shoe covers, head covers, N95 respirators, and face shields (depending on the agent and procedures).

All animal care personnel are provided with work clothes for daily routine wear (usually scrubs), which are laundered in house. All animal care personnel are provided with rubber steel-toed boots or shoes, plastic aprons, heavy rubber gloves, ear protection, goggles, fit-tested respirators and other PPE when required

10 Animal Transportation

Animals traveling to any laboratory or procedural space outside of the animal facilities must be in filter-topped caging on a cart and covered by draping material, a box, or some other secondary container.

11 Congruency Review

The IACUC is required to ensure that all research described in a grant application or proposal is consistent with the corresponding protocol(s) reviewed and approved by the IACUC. Any discrepancies must be resolved prior to the start of the project.

Congruence will be evaluated for several important parts of protocols and proposals. The Vertebrate Animal Section is the primary area of the grant to be compared with the protocol. Information to be reviewed includes:

- General scope of work – disease area, target organs, etc.
- Species of animals
- Number of animals
- Agents administered (including anesthetics, analgesics and experimental agents)
- Procedures to be conducted on animals
- Endpoint(s)

12 Interinstitutional Agreement

Stony Brook University researchers may arrange to carry out portions of research that involve the use of animals via an NIH-funded subcontract from an NIH-awardee (often a private company) that does not itself have an approved Animal Welfare Assurance on file with OLAW. In such situations, OLAW requires that the company apply for an "Interinstitutional Assurance,"

under which SBU assures that the research will be carried out under the terms of its own OLAW-approved Animal Welfare Assurance.

Interinstitutional Assurance Agreements require signatures from the private company, and the Director of the DLAR. If an agreement is necessary, contact the IACUC office at ORC_OVPR@stonybrook.edu. The office will assist with the completion of the form and in obtaining institutional signatures. A sample form is available on request.

13 Collaborating Organizations

The primary PI is responsible for ensuring that all sites engaged in research involving the use of live vertebrate animals have an approved Animal Welfare Assurance and that the activity is covered by IACUC approval. The approval of more than one IACUC is not required if the recipient and performance site(s) have Assurances; **the institutions may exercise discretion in determining which IACUC reviews research protocols and under which institutional program the research will be conducted.**

14 Monitoring

In addition to the mandatory semi-annual inspections (see #15), SBU has a post-approval monitoring program to assess compliance.

The Research Monitor selects protocols to review. This individual is a DLAR employee appropriately trained to conduct this type of process. Using the below Risk Assessment table, at least one “high” level protocol will be chosen per month. Protocols are also selected for cause or as a result of a request by veterinary staff, lab personnel, or the IACUC.

Post Approval Monitoring (PAM) is an opportunity for investigators to request any help or information they may need regarding IACUC processes. The PAM report is maintained by the IACUC office and provided to the IACUC at a fully convened meeting (if necessary). Follow-up PAM visits may be conducted to document that any findings highlighted during a visit have been resolved.

Risk Assessment for Post Approval Monitoring Visits	
High	New Principal Investigator Investigator-maintained Housing Areas History of non-compliance USDA covered species Complex survival surgery USDA pain level “E”
Moderate	Survival surgery – non-complex USDA pain level ”D” Biohazardous agents

Low	Breeding colonies Procedures with no associated pain

USDA Inspections
At least annually, an inspector from the USDA inspects the animal facilities and may inspect individual labs. The inspector meets with the University veterinarian or a designee who escorts the inspector through the facilities. The USDA inspector also reviews IACUC records.

AAALAC International Site Visits
AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. At the request of SBU, AAALAC International visits SBU every three years to assess the animal program.

15 Semi-annual Inspections

The IACUC inspects all the institution's animal housing facilities at least once every six months using the "Guide" and the Animal Welfare Act and Regulations (AWAR) for guidance. All animal housing facilities are inspected, including: satellite facilities (containment areas outside of the central animal facilities where non-USDA-covered animals are housed for more than 24 hours and cared for by researchers), areas in which surgical or behavioral manipulations are performed, animal study areas (locations where USDA-covered animals are held for more than 12 hours), and standard holding facilities.

Facility inspections are conducted every 6 months (June and December). For areas housing non-Animal Welfare Act (AWA)-regulated species, the IACUC may use as few as one qualified individual or *ad hoc* consultant, who need not be an IACUC member, to conduct the facility inspections. Qualified individuals should have training and a working knowledge of the PHS Policy, *Guide*, and the AWARs to appropriately evaluate the facilities and identify deficiencies and animal welfare issues.

For areas housing AWA-regulated species, there should be at least two IACUC members. *Ad hoc* consultants may assist in conducting the inspections. IACUC members involved in these inspections are not required to inspect together and may each inspect different parts of the facility.

Inspection teams are formed based upon the IACUC members request and schedule availability. All IACUC members are allowed to participate in any portion of any inspection. A researcher or facility manager should not be the IACUC inspector for their own lab or facility. Standard operating procedures are made available to the inspection team if requested.

Draft reports of the inspections are prepared according to PHS policy criteria. The IACUC chair communicates observed deficiencies to the appropriate PIs, and requests a timely correction of the deficiencies. The reports and PI responses are submitted to the fully convened IACUC for

review and discussion. The IACUC identifies departures from the PHS Policy and the Guide by referring to those documents as well as the AWA regulations and the Guide. Approved departures are included in the semi-annual report. Deficiencies noted during the semi-annual inspection are categorized by the IACUC as minor or significant and corrective action plans are included in the semi-annual report to the Institutional Official (IO). The research monitor, in cooperation with the University veterinarian, monitors progress on the corrective actions to ensure completion according to the timeline included in the plan. Any minority views are documented and included in the report. IACUC-defined significant deficiencies and corrective actions are reported (please see #16 and #17) to the relevant agencies.

Program Review

The IACUC conducts a program review at least once every six months to evaluate the institution's program for the humane care and use of animals covered by this assurance, using the "Guide" and the AWARs as a basis for evaluation. The IACUC conducts its semi-annual program evaluation by:

- Delegating to the IACUC the initial review of institutional policies for completeness and consistency with all applicable guidelines, utilizing the OLAW Semiannual Program and Facility Review Checklist or the AAALAC Program Description.
- Reviewing reports of protocol monitoring activity to determine if any issues need to be incorporated into the program review.
- Placing special emphasis on animal health and well-being during inspections.
- Integrating issues raised in the IACUC meetings, as well as meetings between the IACUC Coordinator, the IACUC Chair and the DLAR into the program evaluation process.

After review and inspection, a written report (including minority views) is reviewed and signed either in person or electronically by a majority of IACUC members. The report is provided to the IO.

16 Reporting Requirements

16.1 Office of Animal Welfare (OLAW)/NIH

Annual Reporting

This Institution's OLAW reporting period is October 1 - September 30. The IACUC Coordinator will submit an annual report to OLAW on or before December 1st (but after September 30) of each year. The report will include as required:

1. Any program changes since the last report
2. Dates of semiannual evaluations for both the program and the facilities
3. Any minority views filed by members of the IACUC during the reporting cycle
4. Change in IO
5. Change in the IACUC membership
6. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or if AAALAC accreditation is revoked)

Off Cycle Reporting
Prompt reports are required for incidents that have a negative impact on animal health and well-being, while other incidents may be submitted in the annual report.
SBU is required to report to OLAW when projects are federally funded as described in the Animal Welfare Assurance. SBU is not obligated to report when there is no federal funding. The process for investigating and managing serious or continuing noncompliance or serious deviations is the same regardless of funding source. The IO is responsible for submitting these reports. All personal and sensitive information will be redacted from reports prior to submission.

SBU is required to promptly provide OLAW, through the IACUC and IO, 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;* or
3. Any suspension of an activity by the IACUC

Assurance Renewal
The Institution's Assurance with OLAW is required to be renewed every four years. Prior to the expiration date, the Institutional Official will submit the Domestic Animal Welfare Assurance (Domestic Assurance) using the sample domestic assurance template and email it to olawdoa@mail.nih.gov.

16.2 United States Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS)

Annual Research Facility Report
Animal Welfare Act (AWA) regulations require all research registrants to file an Annual Report of Research Facility (APHIS Form 7023) with the USDA's Animal Care program. This annual report documents activities and animal usage for the reporting period of October 1 through September 30. All annual reports are required to be submitted to USDA Animal Care by December 1st of each year through their online reporting system. Even if no animals were held or used during the reporting period, an annual report must be completed and submitted. Annual reports and complaints can be filed with APHIS here - https://www.aphis.usda.gov/awa/research-facility-report/annual-summary

Off Cycle Reporting
It is not a requirement to report serious adverse events and incidents of protocol noncompliance to the USDA. In addition to the above standard reports, the only other additional required reports are:
1. Change in operations (9 CFR 2.30 (c)(1))
2. Protocol suspension (9 CFR 2.31 (d)(7))
3. Uncorrected significant deficiencies from a semi-annual inspection 9 CFR 2.31 (c)(3))

All personal and sensitive information will be redacted from reports prior to submission.

Triennial Registration Renewal
As of December 27, 2021, the USDA removed the administrative requirement to update the research facility registration every 3 years, as it is a duplicative requirement. Facilities are already required to notify APHIS of any change in the name, address, or ownership, or other change in operations affecting its status as a research facility, within 10 days after making such change.

16.3 AAALAC Reporting

Annual Report
Each year in mid-December, the AAALAC International office makes available the online Annual Report form. AAALAC International's Rules of Accreditation require that the Institution submit an Annual Report to maintain accreditation. The annual reports are submitted by the Institutional Official in January of each year.
Annual Reports provide notification of any:

1. Key personnel contact changes
2. Changes in physical areas of supporting animal care and use
3. Actions taken in response to "Suggestions for Improvement" (SFIs)
4. Organizational structure changes
5. Animal usage
6. Protocol violations which had the potential to compromise animal welfare
7. Animal use not approved by the IACUC or comparable oversight body
8. Significant adverse events not previously reported as required by the Rules of Accreditation

Off Cycle Reporting
The following are additional required reports.

1. Adverse events to be reported promptly:
    - Unexpected animal deaths
    - Natural disasters
    - Significant animal rights activities
    - Inappropriate euthanasia techniques and/or failure to confirm euthanasia
    - Allegations/complaints/reports regarding animal welfare concerns
    - Lack of veterinary care
    - OLAW/USDA investigations
2. Other information to be reported promptly:
    - Changes in unit contact (includes changes in degree, title, address, phone and fax numbers, and email)
    - Changes in facility size, location, and/or name if the site visit is pending before the Annual Report is submitted

3. Adverse Event Reports following the IACUC's adverse event assessment. All personal and sensitive information will be redacted from reports prior to submission.

17 Animal Welfare Concerns

It is the responsibility of the Institutional Animal Care and Use Committee (also referred to as IACUC) in accordance with PHS Policy.IV.B.1-8 and 9 CFR.2.31 (c) (1)-(8) and 2.31 (5) (6) & (7) to review and investigate all reports of noncompliance with animal care and use within the institution and to submit a report of its findings and recommendations to the Institutional Official. To exercise this authority the IACUC is empowered to inspect laboratories, procedure areas, animal housing areas, and to sequester research or training records. The IACUC may receive reports in several different ways including external complaints, internal complaints, amendments submitted through myResearch, random and directed site visits, and investigator self-reporting. The IACUC encourages faculty, staff, and/or students to report instances of noncompliance, especially when animal or human health and welfare is in question.

NOTE: This document describes the procedures for handling these matters. This policy is not all encompassing, and the IACUC reserves the right to use its discretion in individual cases.

Definitions
Noncompliance - is defined as the conduct of research in a manner that deviates from the approved protocol or disregards or violates federal regulations or institutional policies. Noncompliance may result from actions or omissions by study personnel and can range from relatively minor or technical deviations to serious deviations that threaten animal welfare.

Serious Noncompliance - is defined as noncompliance that, in the judgment of the IACUC, increases the risk of harm to animals.

Continuing Noncompliance - is defined as a pattern of noncompliance (recurring or ongoing) that, in the judgment of the IACUC, may indicate an underlying deficiency in knowledge of the regulations or IACUC requirements or an unwillingness or inability to comply with these regulations/requirements.

Review Procedures
The investigation of potential noncompliance begins when the IACUC becomes aware of such potential noncompliance. This may include an allegation (unproved assertion) of noncompliance, a self-disclosure of noncompliance, or any other indication that noncompliance may have occurred. The process for the review of potential noncompliance involves initial administrative review by the IACUC chair and veterinarian, followed by an inquiry/fact finding process if indicated. Once complete, the IACUC makes a determination as to whether the noncompliance is serious and/or continuing. The IACUC determination will be documented in a summary report that contains a corrective action plan **in cases of serious and/or continuing**

noncompliance. This process is detailed below, however at any point in the review process, the IACUC may at their discretion:

- Recommend intervention for the safety of animals
- Recommend the suspension of research activities
- Inform, involve, and/or provide documents to the PI, members of the research team, the Department Chair, Dean, or legal counsel, as the circumstances warrant
- Initiate reporting per federal regulations
- Initiate a monitoring visit
- Recommend immediate corrective actions

If the IACUC determines that a potential threat exists to animal health or welfare, the committee may choose to suspend the protocol pending the result of the investigation. All suspensions are reported to the Office of Laboratory Animal Welfare (OLAW) and the Animal Plant and Health Inspection Service (APHIS) via the Institutional Official within 24 hours.

If the IACUC initiates an investigation of the complaint, it can include visiting the site of the problem, interviewing or writing to the PI and study personnel, reviewing questioned procedures, etc. The investigation will be performed thoroughly but expeditiously so as to minimize the potential for threats to animal welfare, or interruptions to research. A report of the findings is discussed at a regularly-convened or expedited meeting of the committee. A course of action to be taken is determined, and a vote taken to approve any action to be recommended. The course of action must be approved by a simple majority of the full committee.

The written recommendations of the IACUC are communicated to the Institutional Official in a timely manner, with any minority opinions attached. Action is then taken according to the recommendations of the Institutional Official. All parties involved are informed of the committee's decision. Following implementation of the committee's actions and resolution of the incident, a final report is generated outlining the complaint, result of the investigation, actions taken and outcome.

Allegations/indications which are determined to have no potential to be serious and/or continuing noncompliance are resolved with either no follow-up (i.e. when an allegation or indication has no merit) or directly with the PI.

Inquiry/Fact Finding Process

If it is determined that the noncompliance has the potential to be serious and/or continuing or if questions remain following the initial review, then an assessment begins. The particular circumstances of the noncompliance determines when the assessment begins and when the IACUC is briefed. The fact finding may be conducted by any designated IACUC member, IACUC Chair or University veterinarian. The IACUC may be briefed at any point throughout the assessment. The assessment continues until there is a determination (i.e. serious and/or

continuing noncompliance). An assessment report is then prepared and includes the recommendation and draft corrective actions. This assessment report will be shared with the PI, and if applicable, other person(s) involved. All parties will be provided with an opportunity to respond to any factual inaccuracies within the report before the committee deliberates.

Deliberation by the IACUC

At a convened meeting, the IACUC will consider all available information and make a determination as to whether the fact finding revealed **serious and/or continuing noncompliance**. The following factors will be taken into consideration by the IACUC in making their initial determination as to whether the noncompliance is serious and/or continuing noncompliance. As each situation is unique, the indicators of noncompliance that are important in one case may not be relevant in other cases.

Factors in the Determination of Serious and/or Continuing Noncompliance:

- Level of risk or potential risk to animals
- Severity of violation of the research process
- Frequency or number of minor deviations or errors
- Intent
- Threat to integrity of the IACUC review processes and requirements for the protection of animals (i.e. falsification of IACUC documents)
- Other factors that, in the judgement of the IACUC, are relevant to the situation being reviewed.
- Similarity of noncompliance to previous deviations and/or noncompliance in other protocols conducted by the investigator.
- Likelihood that instances of noncompliance will continue without intervention

Final Determination of the IACUC

If, in the judgment of the committee, the noncompliance is not serious nor continuing, this determination will be shared with the PI. If, in the judgement of the committee, the noncompliance is serious and/or continuing, the IACUC Coordinator will prepare a summary report including the IACUC's determination and an approved corrective action plan. This report will be shared with the PI, who will be given 14 days to review it before it becomes final.

Corrective Action Plans

The IACUC will develop a proposed plan for corrective actions based on the information gathered during fact-finding and input from the PI and/or other affected individuals. The proposed plan may:

- Require no further action
- Require minor corrective actions to achieve compliance
- Require additional education
- Require the investigator and/or other affected individuals to develop and implement procedures to prevent recurrence

- Review internal departmental or institutional mechanisms and systems for opportunities to prevent recurrence or similar occurrences by others
- Require additional oversight (e.g., by other faculty members or department processes)
- Require more frequent IACUC reviews
- Require internal monitoring visits or monitoring plans
- Suspend or terminate individual protocols
- Restrict researcher's research activities

Required Reporting
When noncompliance is determined to be serious and/or continuing, the final report will be forwarded to federal regulators if required, AAALAC (the institution's accrediting body), and to the Institutional Official, the Departmental Chair, the Dean, and sponsors, if applicable. The IO is responsible for submitting these.

NOTE: The Animal Welfare Act provides specific legal protection for those reporting concerns about animal health or welfare. **No facility employee, committee member, or laboratory personnel shall be discriminated against or be subject to any reprisals for reporting violations of any regulation or standard under the Animal Welfare Act.**

18 Use of Animal Tissues

SBU is committed to reducing the number of animals used in research. Tissue sharing is strongly encouraged as this allows investigators to collect fresh tissue without euthanizing additional animals.

Investigators Donating Tissue
SBU investigators who must euthanize their animals under an approved protocol for experimental requirements are encouraged to donate post-mortem tissue to other SBU investigators, and can do so without prior IACUC review and approval. It is the donating investigator's responsibility to communicate any biosafety issues associated with the tissue. If SBU investigators wish to share tissue outside of SBU, they should contact SBU's Office of Intellectual Property Partners to determine if a Material Transfer Agreement is recommended prior to releasing the tissues. This link can be used for more information. https://www.SBU.edu/spa/material-transfer-agreements-mta.

Investigators Receiving Tissue
SBU investigators who wish to use leftover tissue from other SBU IACUC protocols can do so without submitting a separate tissue protocol. The IACUC does not need to review this activity as all live animal use protocols at SBU have been reviewed and approved previously. The use of the tissue no longer requires review.

SBU investigators wishing to use tissue from institutions outside of SBU should obtain their tissues only from acceptable sources. Acceptable sources would be other institutions that have

obtained IACUC approval for an animal use protocol, preserved specimens from corporate labs, or a USDA inspected slaughterhouse. If the materials come in with a Material Transfer Agreement, SBU researchers need to work with Intellectual Property Partners.

Animal Research that is Conducted in the Field

The IACUC is responsible for oversight of vertebrate animal activities supported by the PHS and those supported by NASA, NSF, and the VA, in accord with PHS Policy. To conduct such activities in the field, the investigator must provide the IACUC with the following information:

- Where the activity will be conducted;
- What procedures will be involved;
- A brief overview of how those procedures are likely to affect the biology and behavior of the individual study animals and their ecology (e.g., surroundings and social settings), the interrelationship of those animals with their habitat and with other species, including the nature and duration of potential effects; and
- An assurance that permit requirements of applicable local, state, national, and international wildlife regulations will be obtained before work begins.

If the IACUC determines that the proposed activity is likely to alter or influence the biology, behavior or ecology of the study animals or other species, then protocol review and approval are required. However, if the IACUC determines that the proposed activity is purely observational *and* will not alter or influence the biology, behavior or ecology of the study animals or other species, IACUC review and approval is *not* required. Investigators are encouraged to consult relevant professional societies, available guidelines, wildlife biologists, and veterinarians, as applicable, in the design of their field studies (*Guide* page 32, Appendix A).

Studies with the potential to impact the health or safety of personnel (*Guide* page 18) or the animal's biology, behavior, ecology or other species may need IACUC oversight, even if described as purely observational. When capture, handling, confinement, transportation, anesthesia, euthanasia, or invasive procedures are involved, IACUC review and approval is required, and the IACUC must ensure that proposed studies are in accord with the PHS Policy and the *Guide* (page 32). A study of free-living wild Animal Welfare Act-regulated species that involves invasive procedures, harm, or otherwise materially alters the biology, behavior, or ecology of an animal under study is covered by the USDA animal welfare regulations and requires IACUC review and approval.

19 Projects Using Recombinant DNA or Infectious Agents

All projects proposing to utilize recombinant DNA or infectious agents require review and approval from the Institutional Biosafety Committee (IBC). PIs may submit an IBC and an IACUC protocol simultaneously; however, release of the IACUC approval is pending until the IBC protocol has been approved. Several individuals are members of both the IACUC and IBC Committees. This helps to support researchers and ensure consistency with safety

recommendations. It is the PI's responsibility to submit the appropriate forms for review to the Institutional Biosafety Committee as well as to complete the appropriate sections in the animal use protocol form.