

Towson University
Institutional Animal Care and Use Committee Procedures

I. OVERVIEW OF THE IACUC PROCESS

The Institutional Animal Care and Use Committee (IACUC) oversees the animal care and use program on the Towson University (TU) campus by providing a humane and compliant environment for all animals used in research and teaching.

The IACUC's policies and procedures are governed by the Animal Welfare Act (AWA), the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy, 1985), and National Institutes of Health's (NIH) Office of Laboratory Animal Welfare's (OLAW) Guide for the Care and Use of Laboratory Animals.

Research, field studies and teaching involving live vertebrate animals, regardless of funding source, conducted under the auspices of TU is reviewed by the IACUC in compliance with federal regulations, its Animal Welfare Assurance (# D16-00454) and institutional policies and procedures.

TU accepts responsibility for the care and use of animals involved in activities covered by the Animal Welfare Assurance. As partial fulfillment of this responsibility, TU will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.

II. RESPONSIBILITIES OF THE COMMITTEE

The IACUC is responsible for oversight of the TU animal care and use program, facilities and its components as described in the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) and the *Guide for the Care and Use of Laboratory Animals* (Guide). The IACUC reports to the Assistant Vice President of Sponsored Programs and Research (Institutional Official) of the university in matters dealing with animal care and use, and oversees compliance with all applicable federal, state, and institutional policies, laws and regulations.

IACUC oversight functions include ongoing assessment of animal care and use. Responsibilities include:

- Review of protocols proposing to use animals in teaching or research.
- Monitoring the use of animals in teaching and/or research at TU animal facilities.
- Review of concerns involving the care and use of animals, including reported violations of the Animal Welfare Act (AWA) and, when warranted, investigation of these concerns.
- Conducting semi-annual evaluation of facilities and the animal care and use program.

- Providing a summary report of these evaluations to the Institutional Official (IO) in accordance with the AWA and PHS Animal Policy.
- Preparing the annual OLAW report.
- Establishing training procedures for scientists, research technicians, animal technicians, and other personnel involved with animal use, care, and treatment.
- When necessary, authorizing suspension of an activity involving animals in accordance with the AWA.
- Review of concerns related to animal care/health and husbandry and making appropriate recommendations to the IO.
- Reviewing Standard Operating Procedures (SOPs) when requested and/or required (e.g. experimental procedures) to ensure that animal laboratories are adequate and that resources are made available for investigators to maintain and update their SOPs when appropriate.

III. RESPONSIBILITIES OF THE OSPR

The OSPR oversees the overall administration of the IACUC. OSPR staffs a research administrator charged with coordinating IACUC meetings, conducting administrative review of newly submitted protocols, and coordinating reviews with the Chairperson, among other duties. Responsibilities of the office include:

- Maintaining the IACUC website and disseminating campus-wide communications.
- Maintaining proper record-keeping of committee activities, protocols, and other related documentation.
- Ensuring IACUC membership and activities adhere to all federal and institutional requirements.
- Serving as the primary contact for USDA inspections and renewing institutional USDA registration.
- Submitting annual OLAW and USDA reports, as well as updating certifications or assurances as needed with the appropriate agencies.
- Housing and monitoring the online Collaborative Institutional Training Initiative (CITI) required of all investigators and animal lab personnel.
- Facilitating the submission and review of protocols and routine communications between the Principal Investigators (PI) and the IACUC.
- Monitoring expiring protocols and notifying PIs of when renewals are due for review.
- Assisting the IACUC in the review of concerns involving the care and use of animals, including reported violations of the Animal Welfare Act (AWA) and, when warranted, investigation of these concerns.

IV. RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

The PI assumes primary responsibility for the care and treatment of all animals used in research or teaching activities under his/her direction. Responsibilities include:

- Maintaining facilities and general animal care compliance. This includes promptly correcting any deficiencies noted in periodic IACUC inspections.

- Ensuring all lab personnel are properly trained and maintain their training certifications according to institutional and federal requirements prior to working with animals.
- Reporting animal health concerns to the attending veterinarian and IACUC.
- Developing and maintaining SOPs for their laboratories.
- Adhering to the approved animal use protocol and submitting annual reports, renewals, and/or notifying the committee of protocol closure.
- Following proper protocols and procedures under the occupational health and safety program of the Environmental Health and Safety (EHS) office.
- Ensuring that all university requirements for student health and safety are followed (e.g. securing signed liability waiver forms for field studies, etc.).
- Acquiring proper permits for field studies when required and requested.
- Maintaining a Drug Enforcement Agency license if utilizing controlled substances.

V. PROCEDURES FOR PREPARING AND FILING A PROTOCOL

A. Prior Review Required

All research involving live animals or materials obtained through invasive procedures must be approved by the IACUC prior to a member of the TU community obtaining animals or utilizing animals in a project. This includes all use of live animals for on-campus research, field research, teaching or testing purposes, as well as all cooperative and collaborative research.

No animals may be ordered for a project until approval has been granted. **No animals may be purchased, housed, or used by an investigator unless an approved protocol is on file with the IACUC.**

B. Qualifications to File a Protocol

All Towson University projects involving the use of animals must be conducted in accordance with an approved protocol. The PI on the protocol must be a member of the TU faculty, staff or student body. Student protocols **must be** sponsored by a faculty member.

All individuals who will be involved in any procedure concerning live animals or data analysis must be listed on the protocol. All personnel must also complete the appropriate institutional training requirements (see section V.C. below) prior to protocol submission. Protocols will not be forwarded to committee members for review until all individuals have completed the necessary training.

1. For the use of animals in foreign countries, approval is contingent on a “letter of assurance” that conditions will either meet local requirements, or in the absence of such requirements, will be assured to be appropriate, must be submitted by the PI to the IACUC.
2. Any change to an already existing protocol must be reviewed and approved by the IACUC prior to implementation. This includes but is not limited to any and all changes to procedures and PI.

C. Training Requirements

Ongoing education and training in protection of animal subjects is required for anyone involved with and engaged in research at TU. The University has partnered with the University of Miami's Collaborative Institutional Training Initiative (CITI) to provide online training to the IACUC, scientists, animal technicians, and all other personnel involved in animal care, treatment or use, on research or testing methods that minimize the number of animals required to obtain valid results and minimize pain and distress.

CITI provides a comprehensive selection of educational modules appropriate for the nature of research with which an investigator is engaged and includes instruction on research or testing methods that minimize the number of animals required to obtain valid results and minimize distress specific to each animal species.

OSPR and the IACUC require ALL individuals engaged in animal subjects research at TU to take the specific CITI training module(s) related to the animal species identified in the protocol plan. Individuals are only required to take the modules most related to the type of research in which they are engaged; however, the IACUC may request additional modules to be completed when reviewing protocols.

The CITI training must be completed every three (3) years in order to continue conducting animal research at Towson University. This training is monitored by OSPR, and any research assistant training is continually monitored by the PI and Lab Manager.

D. Protocol Submission and Review Process

1. Initial Submission

The OSPR will conduct an initial administrative review of the application for completeness before forwarding it for further review. This includes ensuring that animal use training has been completed by the PI and all members of the research team. Once the initial administrative review has been completed and the application processed, and forwarded to the IACUC for review, the OSPR will notify the investigator in writing of their protocol tracking number and any additional information required.

2. Designated Member Reviews & Full Committee Reviews

All protocols are distributed to all members of the IACUC as required by regulation. The protocol details information on the species to be used, the projected number of animals required, the source and transportation of the animals, the method of euthanasia, and whether the animals are used for teaching or research purposes, as well as any planned departures from the *Guide*. Investigators are required to provide a justification

for the selection of the animal model, for the number of animals required, and provide a description of the experimental manipulations to which the animals will be subjected.

Designated Member Reviews

Applications for research involving rodents or non-covered USDA species may be reviewed through an expedited process – wherein a designated member reviews the application - unless complex survival surgery is involved. Designated member reviews (DMRs) typically follow a two- to three-week timeline.

All members of the IACUC are invited to comment on each protocol, however, two members serve as designated member reviewers, in addition to the Veterinarian. The Research Compliance Administrator recommends the Designated Reviewer(s) DR(s) to the Chairperson, who then approves or rejects the recommendation by email. After the Chairperson has approved the recommendation or suggested alternative DRs, the committee has a two- to three-week review timeline to comment and request full committee review (FCR) before it continues on to DMR approval.

Any member of the IACUC may request a protocol be subject to FCR. If no such request is made to the Chairperson, the DRs recommend whether the protocol should be approved as written, submitted with changes to address specific concerns, or referred for FCR. If there are additional modifications required to secure approval through DMR, each DR will review identical copies of the revised protocol until each has clarified that their concerns have been addressed and have confirmed approval of the modified protocol.

Full Committee Reviews

If the proposed species is a USDA covered vertebrate animal (e.g. rabbits, non-human primates, canines, and pigs) then FCR will be scheduled at the committee's earliest convenience to discuss the protocol.

The IACUC meets as often as necessary to review all protocols which require full committee review. FCR must occur at a convened meeting with a quorum present and a majority vote to approve, require modifications to secure approval, or withhold approval. All reviews, communications, recommendations, minority opinions and the final vote are documented through the Research Compliance Administrator. The Administrator prepares a letter notifying the investigator of the actions of the IACUC; the letter is signed by the IACUC Chairperson.

Possible outcomes of the full committee review are: 1) Protocol Approved; 2) Protocol requires modification (to DMR); 3) Protocol approval is withheld or deferred pending changes, with resubmission to FCR. If the protocol requires modifications to secure approval, the members present at a full committee meeting may decide by unanimous vote to have the resubmitted protocol reviewed by DMR (appointed by the Chairperson) or returned for FCR at a convened meeting. If all members of the IACUC are not present at the meeting, the committee may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, all members of the

IACUC are provided a copy of the revised protocol that is resubmitted for DMR and have the option to request FCR.

For FCR, it is determined prior to the meeting if a member will need to be recused at any point. If so, it is ensured that enough voting members will be present so that the quorum will be maintained.

All reviewers and review comments are kept anonymous throughout the review process unless a reviewer has offered to discuss comments with the PI directly. In addition, the Veterinarian may submit comments that require the PI to consult them for additional information.

3. Application Approval or Disapproval

a. Approved.

Upon approval, the PI is notified in writing. Approval is granted for three years. Once approval is received, animals may be purchased and used as specified in the protocol. The PI must submit annual progress reports on the research and must submit a new protocol when the triennial review is due.

b. Disapproved

If the committee did not approve the protocol, a new revised protocol must be submitted to the committee. The PI may wish to contact the IACUC Chairperson and/or Veterinarian for more information.

4. Modifications to Existing Approved Protocols

Modifications are accepted and reviewed on a rolling basis. All modifications must be submitted to the IACUC for review and approval. Changes may not be made until the committee has approved them. The following must be submitted:

- a. A completed Application for Modifications to an Approved Protocol Form.
- b. An attached document clarifying the goals and methods described in the original protocol, as well as specific modifications and/or additions/deletions. If requesting additional animals, PIs need to provide a rationale for the increase in animal census. Applicable resources and a completed literature search must be included in the modification.

5. Annual Reviews, Expirations and Protocol Inactivation

a. Annual Reviews

Protocols are approved for a three-year period. USDA Animal Welfare Regulations require that the IACUC conduct continuing reviews of activities involving live animals not less often than once per year. The Public Health Service Policy requires

that the IACUC conduct a complete review of all previously approved ongoing activities at least once every three years.

TU's IACUC complies with these requirements by:

- i. Allowing two annual reviews that are performed by the IACUC (either administratively or by full committee depending on species) on the first and second anniversary of the original approval.
- ii. Complete resubmission of the protocol for FCR every three years.

b. Expirations and Renewals

The OSPR will contact the PI prior to the three year expiration date with a reminder that a new form must be submitted for the study to remain active. Although the OSPR will send out these reminders, it is the PI's responsibility to monitor the status of any protocols on file and to submit the renewal on time. If insufficient time is available for the protocol renewal to be completed the research must be put on hold. In such cases, continued use of live animals is not permitted.

In the absence of an approved protocol, the privilege of maintaining animals in the animal facilities may be forfeited.

To continue to use the procedures described in the original protocol, a new protocol review form must be filed and approved, regardless of whether or not there are any changes from the previously approved protocol. This protocol will be reviewed by the committee, and, if approved, will be valid for an additional three more years.

c. Inactivation of a Protocol

The PI must inform the IACUC by contacting the OSPR if the work being conducted in a protocol has been completed or terminated.

VI. OVERSIGHT OF ANIMAL CARE & LABORATORY MAINTENANCE

A. Responsibility for Animal Care

The PI assumes primary responsibility for the care and treatment of all animals used in research or teaching activities under his/her direction. The PI shall properly care for animals at all times and ensure that all lab personnel have completed appropriate training. While staff or students employed in the laboratory provide routine care and husbandry on a daily basis, the PI must provide any and all special care to animals involved in research. This is especially critical for animals requiring frequent supervision during periods of experimental preparation, treatment and/or recovery. It is the responsibility of the PI to provide adequate post-operative care. Lab personnel act as support service for maintenance of animals and should never be relied upon for primary supervision of animals.

B. Lab Maintenance Expectations

The IACUC expects that all facilities maintain general animal care compliance in accordance with all laws, regulations and policies as outlined by PHS and OLAW. The IACUC conducts periodic inspections to ensure that lab facilities are maintained. The inspection includes but is not limited to ensuring:

- feeding and cleaning logs are maintained
- all food, medicines, and supplements are not exceeding expiration dates
- appropriate protective gear and laboratory procedures are in place and visible to laboratory personnel. If lab personnel are on site during an inspection appropriate gear is in use.
- emergency contact information is placed in a visible and accessible location for laboratory personnel
- housing requirements are appropriate for the species being housed

SOPs should be developed by the PI, any personnel charged with managing and operating the laboratory and, if applicable, in conjunction with the IACUC. SOPs should be regularly maintained and updated on a routine basis, and placed in a visible area within the laboratory in the event of an emergency.

C. Unanticipated Events and Animal-Related Concerns

For health concerns, the Reporting Animal Health Problems SOP must be followed by all husbandry staff and laboratory personnel to ensure proper reporting procedures. This is available on the IACUC website. It requires completing an Animal Health Evaluation Report and immediately contacting the Institution's Veterinarian for emergency care and instruction. The SOP includes multiple numbers for the primary veterinarian as well as the backup veterinarian.

Further, copies of the Animal Health Evaluation Report and a written description of the concern is emailed to the IACUC at ospr@towson.edu. Anonymity of the individual initiating the concern is respected, if requested and if possible.

The IACUC will review each concern it receives and, if warranted, take appropriate corrective actions to ensure that laboratory animals continue to receive humane care and use in accordance with the highest ethical standards, laws, regulations, and policies. Based on the severity and urgency of the reported concern, the Veterinarian and the Chairperson may convene the full IACUC to review the concern(s), determine the action to be taken, and immediately notify the PI of such action.

The IACUC replies in writing to all written concern or complaint it receives. All reports are filed with IACUC records and when required, reported to OLAW.

D. Disaster Preparedness

Emergencies, accidents, and injuries can occur at any time, without warning. The ability to respond to emergencies is a responsibility of the TU community to prepare for, respond to, mitigate and recover from various critical incidents, major events, emergencies, or disasters that may affect lives, property, and the institution. Sufficient preparation is the critical key to successful mitigation of emergencies. Each individual responsible for animal care should

review and be familiar with workplace evacuation routes, equipment and supplies prior to an actual emergency.

The *Guide for the Care and Use of Laboratory Animals* as well as the Office of Laboratory Animal Welfare (OLAW) describe the requirements of disaster planning as well as offer resources for institutions to take into account the well-being of animals and personnel during unexpected events.

Facility personnel and animal users should be familiar with the institution's procedures in the event of emergencies. PIs, facility managers, and animal caretakers have shared responsibilities to develop and follow facility (SOPs and contingency plans of appropriate husbandry and health monitoring of all animals. The TU Attending Veterinarian is available at any time to address questions or concerns. Any variation to the status of animals must be reported immediately to the veterinarian and the IACUC.

VII. GRANT PROCEDURES

All grants that involve the use of animals must have an approved or pending protocol on file with the IACUC. Depending on the sponsor, an approved protocol may be required prior to submission or prior to the release of an award (e.g. "Just-In-Time" processing (JIT) by NIH). In addition, the Public Health Service (PHS) policy, and other funding agencies, require that institutions verify congruence between those components of the grant applications related to animal care and use and approved IACUC protocol(s). If there are changes to the proposed animal work, the PI must submit an amendment to the IACUC listing these changes. PIs should be mindful of which is required by the sponsor so the IACUC may review and approve the protocol(s) and grant proposal in a timely manner.

It is the PIs responsibility to ensure that they follow all requirements outlined by the sponsor while complying with all applicable animal regulations and the approved IACUC protocol. Failure to do so may result in the protocol being put on hold or suspended, and/or holding of the award's funds.

Upon receipt of the award, the PI must notify the IACUC of the applicable protocol. If there are any changes to the protocol, an amendment must be submitted. If no protocol is on file, a new protocol form must be submitted and approved before funds are made available to the investigator.

VIII. PROCEDURES FOR COMMITTEE INSPECTION OF INSTITUTIONAL ANIMAL FACILITIES

A. Inspection Frequency

The Committee will inspect the University's animal facilities and areas of animal use in research projects (investigator's laboratories) at least once every six months to ensure compliance with all appropriate Federal, State, and Institutional guidelines, as well as to ensure compliance in the procedures outlined in the approved protocol. This includes all animal holding areas, common use facilities, and individual study areas.

B. Inspection Reports and Subsequent Actions

The Research Compliance Administrator assists the IACUC by preparing minutes of the meetings, and collecting notes/commentary made by the IACUC during the facility inspections. Deficiencies noted in the report are designated as minor or significant with required corrective actions, as well as any minority opinions. Once finalized, the draft report is circulated electronically to the IACUC for final review and signature approval. The IACUC has one week to review with the opportunity to note any other minority opinions. Supplemental documentation for IACUC signatures is provided with email records. Review and signature is required by the majority of the IACUC before the IACUC Chairperson and Compliance Administrator may forward to the IO. The reports are shared electronically with all IACUC members, and a copy of all reports are maintained by the OSPR and are available to OLAW upon request.

The report includes any deficiencies identified during the facility inspection, as well as any departures from the guide. Deficiencies noted in the report are designated as minor or significant with required corrective actions, as well as any minority opinions. A minor deficiency would not have an impact on the health of the animals while a significant deficiency may be a threat to the health or welfare of the animals. The PI and department chairperson each receive a notice from the IO with the outcome of the inspection with any required corrective actions. These notices specify a plan and timeframe to remedy the deficiency.

The Administrator forwards follow-up reports on significant deficiencies to the IACUC and IO for review and approval. In the case of minor deficiencies, follow-up reports are reviewed during the next scheduled meeting. If significant deficiencies have not been corrected, senior leadership will be notified and the IACUC may discuss temporary holding of research until all concerns have been addressed.

Progress toward rectifying each deficiency will be monitored at subsequent Committee meetings until the situation is completely resolved. A report of all inspections, any deficiencies noted and the manner in which these were dealt with will be made semi-annually to the IO after each facility inspection.

IX. REPORTING MISTREATMENT OF ANIMALS OR NON-COMPLIANCE WITH IACUC REQUIREMENTS

A. Reporting of Mistreatment or Non-Compliance

Anyone who suspects that animals are being mistreated or appropriate procedures are not being followed related to the use of animals in any Towson University laboratory or program should report their concerns. They may do so anonymously or by contacting the SpeakTU hotline:

Towson University has procedures in place for individuals to report illegal, unethical, or improper conduct through an Ethics and Compliance Hotline, providing an additional avenue

for reporting concerns. SpeakTU is available 24 hours/7 days a week for reporting unethical conduct by telephone or online. Regardless of the method used to report concerns, individuals may choose to remain anonymous. Further, as a constituent institution of the University System of Maryland (USM), whistleblowers are protected against retaliation not only by federal requirements but also by University, USM, and State of Maryland policies and regulation.

Anonymity of the individual expressing the concern will be respected if requested. If appropriate, the matter will be referred to the IO and/or Provost of the university.

B. Protection for Whistleblowers

Individuals who report allegations of mistreatment or non-compliance with IACUC regulations will be protected. The OSPR and the IACUC will ensure that proper protections are in place for any individual who reports any mistreatment or non-compliance, and that appropriate review and action will be taken to maintain proper animal care.

This is visibly posted on the IACUC website along with information on how to report a concern involving the care and use of animals in all animal facilities. Any individual can report a concern regarding animal procedures and/or animal care to the Office of Sponsored Programs and Research (OSPR) via email (ospr@towson.edu) or phone (410- 704-2236). In addition, they may also directly contact the IACUC Chairperson, Attending Veterinarian, Research Compliance Administrator, or IO.