



**Institutional Animal Care and Use Committee
Policies and Procedures**

November 2019

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1.0 INTRODUCTION

This manual is intended to be used as a guide for University Massachusetts Lowell (UMass Lowell) faculty, staff, and students who use animals in research, testing, and instruction. The policies outlined herein are based on recommendations provided in the reference materials from the National Research Council, Applied Research Ethics National Association, Office of Laboratory Animal Welfare, and the IACUC Handbook. Activities involving animal use are regulated by the federal government and the UMass Lowell Institutional Animal Care and Use Committee (IACUC). The IACUC is appointed by an Institutional Official (IO) to ensure compliance with all federal, state, and institutional regulations. This document outlines the policies and procedures that the IACUC and UMass Lowell community must follow to meet these regulatory requirements. It is intended to communicate information to make the process easier for those involved in animal care and use at UMass Lowell. While recognizing the importance of using live animals for research, testing, and instruction, UMass Lowell, for both ethical and scientific reasons, insists upon the highest standards for the care and use of such animals. It is in the best interest of both the Institution and the IACUC to regard itself as a bioethics committee rather than a unit merely to comply with federal policy. It is the responsibility of each individual using and/or caring for animals to be familiar with, and to ensure compliance with, these standards and to use animals in an ethically responsible way. This document is subject to changes and/or updates as rules, regulations, or policies change.

The public may request, at any time, information regarding animal research at UMass Lowell. This is in part why protocol review forms must be written in language that the public can understand. The regulations also require the IACUC include a member of the general community who is not affiliated with the institution in any way and at least one non-scientist. Therefore, protocols must be written to clearly and accurately describe the procedures being used and the reasons for the research in simple language so that the non-scientists on the IACUC can understand and review the proposed research.

As required by law, UMass Lowell has on file with the PHS Office of Laboratory Animal Welfare (OLAW), an **Assurance of Compliance with Public Health Service Policy on Humane Care and Use of Laboratory Animals**, hereinafter referred to as the Assurance. It is the document that describes to the federal government the UMass Lowell program of animal care and use and the assurance that UMass Lowell will comply with the standards outlined within. The Assurance is signed by the UMass Lowell Institutional Official and obligates UMass Lowell to comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy. The Assurance is valid for a period of up to five years, at which time a new Assurance must be submitted to OLAW. Without an applicable PHS-approved Assurance, no PHS-conducted or supported activity involving animals at the Institution will be permitted to continue. UMass Lowell is a Category 2 Institution, indicating that the IACUC is required to report on the program and inspect the animal facilities to meet all regulatory standards.

2.0 FEDERAL LAWS, REGULATIONS, AND GUIDELINES

The privilege of using animals in research and the common concern for the care and welfare of laboratory animals used in research and testing falls under the jurisdiction of three different government agencies and is subject to three Congressional Acts. The primary responsibility for the **Animal Welfare Act (AWA)** is assigned to the U.S. Department of Agriculture, Animal and Plant Health Inspection Service. This act details requirements for the care and use of animals in research, testing and education. The AWA applies to all warm blooded animals used in biomedical research except for purpose-bred rats and mice, birds, and farm animals used in agricultural production research. Institutions are licensed and must report yearly their animal use and describe their animal care program. Implementing regulations of the AWA are established in the Code of Federal Regulations, Title 9, Chapter 1, Subchapter A, Parts 1, 2, and 3. Unannounced inspections of facilities covered by the AWA are performed annually by the USDA APHIS Inspector. UMASS LOWELL is licensed as a research institution by USDA and the Research Facility Registration number is 14-R-0081

The U.S. Department of Health and Human Services, **Food and Drug Administration**, is also involved in ensuring proper procedures for the care and use of laboratory animals. Regulations are implemented under the Federal Food, Drug, and Cosmetic Act as implemented by the Good Laboratory Practice Regulations (21 CFR Part 58). The U.S. Department of Health and Human Services, **National Institutes of Health**, is responsible for the implementation and general administration of the **Public Health Service Policy** on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy implements the **Health Research Extension Act of 1985** (Public Law 99-158), and is based on the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. The PHS Policy and Health Research Extension Act apply to all institutions receiving animal research funds from NIH and NSF and cover **all** vertebrate species. Policies and procedures at UMass Lowell are structured to cover all vertebrate species and all PIs using vertebrate animals are required to follow these guidelines, regardless of funding sources. Any animals housed in UMass Lowell facilities will fall under the policies and procedures as set forth in this document. Institutions must either have AAALAC accreditation or an NIH Assurance Statement on file at OLAW/NIH. Animal care and use facilities must be built and operated in compliance with the recommendations of the Institute for Laboratory Animal Resources “**Guide for the Care and Use of Laboratory Animals**”.

Yearly reports on the status of the animal care program required by both the USDA and PHS. UMass Lowell has a PHS Assurance and the Assurance Number is A3867-01. UMass Lowell requires that the policies and procedures and compliance requirements are followed for all vertebrate species used at UMass Lowell, whether covered under USDA or PHS Policy and regardless of funding sources, to allow for uniform compliance and enforcement policies.

3.0 INSTITUTIONAL POLICY AND APPLICABILITY

The Assurance states that UMass Lowell will:

- Comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

- Follow the “U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.”
- Acknowledge and accept responsibility for the care and use of animals involved in activities covered by the Assurance. UMass Lowell will make a reasonable effort to 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. Oversight is provided by an Institutional Animal Care and Use Committee appointed by the Institutional Official.
- Provide a safe work environment.
- Establish and maintain a program for activities involving animals in accordance with the “Guide for the Care and Use of Laboratory Animals”.

The Assurance and the information in this document apply to all activities involving animals that are:

- Sponsored and unsponsored research by UMass Lowell and other funding agencies,
- Conducted by or under the direction of any employee, student, or agent of UMass Lowell in connection with his or her individual UMass Lowell responsibilities,
- Conducted by or under the direction of any employee, student, or agent of UMass Lowell involving the use of any UMass Lowell property or facility, or
- Involving any collaborating, subgranting, or subcontracting individual or institution working with UMass Lowell.

Activities involving animals covered by the Assurance and the UMass Lowell Policies and Guidelines for the Care and Use of Animals must be conducted in facilities approved by the UMass Lowell IACUC. The guidelines apply to all use of animals at UMass Lowell, regardless of whether the activity is funded or not. The purpose is to ensure that humane care and use of animals in research, testing, and instruction is provided at all times and that all applicable laws, standards, and policies affecting such use are followed. Research protocols that involve animals should be written to ensure animals lives are used for a good purpose and the science proposed warrants that use.

4.0 FACILITY MANAGEMENT AND PER DIEMS

Policy and federal guidelines require that living conditions for research animals are appropriate for their species and contribute to their health and comfort. Accurate records are kept regarding all aspects of animal management. Specific information related to UMass Lowell animal care and use is provided upon request and some information is included in the UMass Lowell IACUC Policies and Procedures. Standard Operating Procedures (SOPs) and reporting forms are available in the animal care facility and all IACUC-approved facilities. Information is also available from the Office of Research Integrity. Oversight of all animals is directed by a veterinarian or other professional trained in animal care and medicine.

Per Diem Charges

Per Diem fees have been implemented and apply to all protocols. Rates will be re-evaluated periodically and communicated to all PIs.

5.0 DEFINITIONS

Activities: Include, but are not limited to, research, research training, biological testing, and instruction of students.

Amendment: A technical description of a proposed change to a previously approved protocol.

Animal: PHS Policy defines an animal as “any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing, or for related purposes”. The Animal Welfare Act Regulations (AWAR) define an animal as “any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded animal, which is being used or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. This term excludes birds, and rats and mice bred for use in research.” **The UMass Lowell IACUC ensures the campus is in compliance with all regulations by applying the PHS and OLAW regulations to all vertebrate animal use on campus for teaching and research.** Studies involving dead animals require reporting and justification to the IACUC but the IACUC does not require the PI to report the use of dead animals via a protocol unless the animals are killed for the purpose of the research or teaching activity. The UMass Lowell IACUC considers embryos and fetuses as vertebrate animals if their central nervous system is sufficiently developed to feel pain. The UMass Lowell IACUC has adopted an institutional-wide Assurance, which means that the policies stated herein apply to **all** vertebrate animal use in research and teaching.

Animal Facility: An animal facility is any and all areas, buildings, enclosures, rooms or vehicles, including satellite facilities used for: animal confinement, breeding, experiments including surgical manipulation, maintenance or transport. Animals may be held outside an animal holding facility for a period of less than 12 hours without IACUC approval except for survival surgery areas. Locations where animals are held for more than 12 hours become a satellite facility requiring justification of, and prior approval by, the IACUC, and approval of husbandry plans and physical plant.

Animal Welfare Act (AWA): Public Law 89-544, 1966, as amended (P.L. 91-579, P.L. 94-279, and P.L. 99-198) 7 U.S.C. 2131 Et. Seq. Implementing regulations are published in the Code of Federal Regulations (CFR, Title 9, Chapter 1, Subchapter A, parts 1,2, and 3) and are administered by the U.S. Department of Agriculture.

Assurance: Assurance of Compliance with the U.S. Public Health Service Policy on Humane Care and Use of Laboratory Animals.

Care and Use: Petting, feeding, watering, cleaning, manipulating, loading, crating, shifting, transferring, immobilizing, restraining, treating, training, working and moving, or any similar activity with respect to any animal.

Designated Representative – A project representative is someone appointed by the principal investigator to direct or oversee the project. Even though the PI may appoint someone to this role, the PI holds final responsibility for all aspects of the project.

Guide: The Guide for the Care and Use of Laboratory Animals, National Academy Press, 2011, Washington, D.C. or succeeding revised editions.

Institutional Animal Care and Use Committee (IACUC): The IACUC reviews and approves animal use protocols.

Institutional Official (IO): An individual who signs, and has the authority to sign, the Institution's Assurance, making a commitment on behalf of the institution that the requirements of the PHS Policy will be met.

Mistreatment: Wrongful or abusive physical or psychological treatment of an animal.

Noncompliance: Failure to follow federal, state, local, or institutional regulations or fulfill official requirements. IACUC has the legal authority to stop a research project, either temporarily or permanently, if noncompliance continues. The IO can initiate additional disciplinary action involving academic oversight authorities. Noncompliance must be reported to the IO, who must then report it to the PHS.

Principal Investigator (PI): Only full-time UMass Lowell faculty members and qualified employees may serve as project directors/leaders for activities that involve animals. The PI accepts full responsibility for all aspects of the project.

Protocol – A technical overview of the animal care and use portions of a research project. Only full-time faculty members or qualified staff at UMass Lowell that are sufficiently experienced in animal procedures are qualified to submit a protocol.

Public Health Service (PHS): The Public Health Service includes the Alcohol, Drug Abuse and Mental Health Administration; the Centers for Disease Control; the Food and Drug Administration; the Health Resources and Services Administration; the National Institutes of Health; and the Office of the Assistant Secretary for Health, Department of Health and Human Services.

Quorum: A majority (>50%) of the voting members of the IACUC. Certain official actions of the IACUC, such as full committee review of a research project or suspension of an activity, require a quorum. Abstentions from voting do not alter the quorum or change the number of votes required. For example, if the IACUC consists of 12 voting members and 8 are present at a particular meeting, approval of a protocol would require a minimum of 5 votes whether or not there are any abstentions.

Satellite Facility: A "satellite" laboratory animal facility is any containment outside of a core facility, centrally designated or managed area in which animals are housed for more than 12 hours.

Violation: Disregard for or infringement of the rules or regulations.

Zoonosis: A disease communicable from animals to humans under natural conditions.

6.0 ROLES AND RESPONSIBILITIES

Consulting/Attending Veterinarian (AV) – The Veterinarian is chiefly responsible to provide for the health and welfare of the animals used at UMass Lowell. The Veterinarian must have the experience, training and expertise necessary to appropriately evaluate the health and well-being of the species in the context of the animal use at the institution. The AV at UMass Lowell is contracted to provide services through a consulting agreement and should have the formal education necessary to be a doctor of veterinary medicine.

Responsibilities of the IACUC AV include but are not limited to

- Serving on the IACUC
- Providing veterinary care and consultation as needed for general medical care and on the recognition and palliation of pain
- Reviewing protocols and making recommendations to the IACUC regarding animal welfare issues related to proposed research activities
- Serving on the Pre-Review Committee to review and make recommendations on protocols to be submitted for full board review
- Consulting with researchers and the IACUC to provide information about alternative procedures to reduce pain and distress
- Advising the IACUC on new procedures that will help to reduce or eliminate the potential to cause pain and distress.
- Serving as a resource for IACUC members, PIs, graduate students on issues related to animal welfare
- Providing expertise on matters of animal health and welfare, including, but not limited to: use of proper anesthesia and analgesia in laboratory animals in the relief of pain and distress; discussion of the possible complications related to procedures used or a disease model proposed; provide a review of the plans for appropriate and timely medical intervention.
- Authorizing a halt to any animal activities in question until an investigation can be performed.
- Authorizing euthanasia for any animal in pain or distress that cannot be otherwise alleviated.
- Recommending humane use of the animals while ensuring the scientific requirements of the study are met.
- Assisting with training and education of ORS Manager, IACUC members, PIs, students, etc. as needed.
- Assisting with oversight of satellite animal facilities and providing recommendations on facility design to meet or exceed regulatory standards for the care and use of laboratory animals in teaching and research.
- Participate in semi-annual facility inspections and program reviews
- Review IACUC Policies and Procedures, PHS OLAW Assurance, and other documents as needed that are related to regulatory compliance
- Providing emergency services as required.

The AV maintains close communications with the IACUC Chair, Animal Research Compliance Manager (IACUC Administrator), and the IO. The AV has delegated authority program authority and direct access to the IO to discuss IACUC related issues.

Institutional Official (IO) – The individual whom the Institution has given the authority and responsibility to enforce and supervise that the requirements of the Animal Welfare Act and the Public Health Service policy will be met. This individual for UMass Lowell is the Associate Vice Chancellor for Research Administration and Institutional Compliance. The IO also insures that activities involving the care and use of animals at UMass Lowell are humane and in compliance with all applicable regulations and internal policies. The IO appoints committee members, defines and assigns responsibilities and reporting channels, and reviews the routine inspection and committee reports. The IO is responsible for reporting noncompliance to the PHS.

IACUC – A standing committee, appointed by the IO, comprised of members of the UMass Lowell community and the general public. The IACUC is charged under the Animal Welfare Act with representing “...society's concerns regarding the welfare of animal subjects ...”. The IACUC has adopted uniform policies that apply to all vertebrate animals used in research and teaching regardless of whether the species are covered by the AWAR or PHS. The committee must consist of at least 5 members and shall include at least one Doctor of Veterinary Medicine, one practicing scientist experienced in research involving animals, one member whose primary concerns are in a nonscientific area, and one individual who is not affiliated with UMass Lowell in any way – other than as a member of IACUC. An individual who meets the requirements of more than one of these categories may fulfill more than one requirement as long of the committee consists of at least 5 members. The IACUC is responsible for reviewing all research, testing, and instructional protocols involving animals, conducting semiannual reviews of the UMass Lowell program and its facilities, reviewing and addressing concerns involving animals in research, testing, and instruction, and advising the IO on all aspects of the animal program and facilities. A decision to deny approval may not be overruled by the IO but the IO can decide to not allow an approved project to proceed. The IACUC is also authorized to investigate concerns involving the care and use of animals and has the authority to suspend an activity involving animals if it determines that the activity is not being conducted in accordance with a description of the activity approved by the IACUC.

IACUC members are required to keep all information related to research applications confidential. This means that information reviewed which may be sensitive in nature, should not be discussed outside of the review process or discussed in a place where the discussion might be overheard.

Animal Research Compliance Manager and IACUC Administration – The Compliance Manager oversees all facility operations and also serves as the IACUC Administrator. The Animal Research Compliance Manager reports to the Director of Research Integrity. It is important that the Manager understand animal welfare laws, regulations, and policies to provide stability and continuity to the animal care and use program. The Animal Research Compliance Manager is responsible for all IACUC related communication, reporting, and tracking.

Responsibilities for IACUC Administration include but are not limited to

- Assists PIs to understand the required steps for protocol submission, provide forms, and fields questions related to protocol amendments, renewals, and ongoing activities
- Assists IACUC members by disseminating information for meetings and serving as a central contact point
- Manages, maintains, and tracks all IACUC protocol-related documents and correspondence including pre-review comments, assigns protocol and amendment numbers, and issues approval letters
- Screens new protocols for completeness and transfers appropriate information between pre-review subcommittee and PIs
- Schedules meeting times and locations, drafts agendas, attends meetings, and takes meeting minutes and disseminates all information to appropriate parties
- Assists with preparation and submission of all regulatory-related documentation including OLAW Assurance, PHS Semi-Annual reports, USDA reports and registration, drug licensing information, etc. with approval from IACUC Chair and/or IO
- Manages computer database for tracking and reporting IACUC protocols and activities, training information, renewal reminders, etc.
- Maintains files (electronic and hard-copies) of all IACUC documents, archives inactive protocol files, and destroys outdated documents either more than 3 years after they are generated or three years after cessation of the activity
- Monitors, notifies PIs, and tracks annual protocol review and 3-year re-submission due dates
- Tracks numbers of animals used and allowed on protocols for both reporting and procurement purposes
- Prepares Member Packets for new IACUC members
- Coordinates procurement of animals after IACUC approval

Responsibilities for facility operations include ensuring animals receive proper care and housing and that all regulatory requirements are met. The Manager oversees facility operations (and assists with oversight of satellite facilities) to control the environmental factors that are essential for animal well-being.

Responsibilities include but are not limited to

- Conducting routine daily inspections of all animal holding and support facilities and equipment to maintain animal health, facility condition, sanitation, and environmental parameters
- Assisting in development and implementation of standard operating procedures for full compliance with all state, federal, and local regulatory compliance requirements
- Maintaining, generating, and submitting facility records and documentation necessary for reporting
- Coordinating maintenance of physical environment
- Supervising students or staff that work in the facility, assign work schedules, ensures all UMass Lowell performance standards are met and that required duties are completed
- Participating as required in budget development for equipment, supplies, and personnel to ensure effective operations of the facility

- Coordinating research projects and scheduling space usage for the facility
- Providing hands-on training activities and appropriate supervision to build competence among those using the facility
- Verifying proficiency in all various procedures to be used in live animals and signing off on training records to indicate individuals have completed and demonstrated proficiency in the procedures to be used in live animals
- Provides oversight of controlled substances, maintains logs to document receipt of and use of substances, and distributing substances to researchers who have requested materials listed on their IACUC-approved protocol
- Provides information to assist PI/students on appropriate dosages/dilutions for anesthetics and analgesics
- Ensuring UMass Lowell safety policies and procedures are adhered to including those related to biological and radioactive materials
- Participating in meetings with UMass Lowell staff, the IACUC, and IACUC Chair to keep them informed of current and future projects, policies, and procedures
- Coordinating movement of animals throughout the facility and intake of new animals
- Assisting in other duties as assigned to complete required work

The Manager is in frequent communication with the Director of Research Integrity, IACUC Chair, and Attending Veterinarian (AV) to facilitate protocol submissions and amendments, animal care and use, and the general conditions of the facility environment. The Manager must have a working knowledge of laboratory animal facility operations, be able to communicate effectively, and demonstrate the ability to adapt and respond in a timely and respectful manner to the needs of faculty, students, and staff.

The Animal Research Compliance Manager is not expected to be involved in or engaged in any research activities but rather support as much as possible the researchers who use the facility. All research activities and procedures are the responsibility of the PI. Training necessary for non-routine and research specific procedures that have been outlined in the protocol and approved by the IACUC, are expected to be provided by the PI to ensure their research staff and students are appropriately trained and proficient in such procedures. In some cases, routine procedures, such as blood collection, may be provided by the Animal Research Compliance Manager. The PI will be charged for the procedure(s) as outlined in the Per Diems and Service Fees document. Such arrangements must be made in advance of the date of the procedure.

IACUC Chair –The person serving as the IACUC Chair must possess the leadership skills to oversee the coordination and implementation of effective, efficient systems for IACUC protocol and program review in compliance with the PHS Policy and AWAR. The Chair must have full support of the Institutional Official (IO), be able to communicate directly with the IO, and be of sufficient stature within the institution (typically a tenured faculty) to perform the function of the position without jeopardy to his/her career or position. The Chair typically serves for a 3-year term and is typically succeeded by the Vice-Chair. The Chair’s IACUC responsibilities include the following:

- Convenes and chairs meetings
- Ensures that a quorum is present and declares the loss of a quorum resulting in the end of official business if sufficient numbers of members depart a meeting

- Identifies any conflicts of interest before meetings and protocol review begins
- Reviews official IACUC documents including meeting minutes, protocols, semi-annual program reviews and inspection reports, amendments
- Authorization to approve protocol minor amendments or issue a suspension or cessation of research activities if warranted.
- Ensures that semiannual program reviews are performed and appropriately documented
- Serves as spokesperson on behalf of the IACUC, both internally and externally
- Coordinates IACUC subcommittees
- Participates in investigations of reports of noncompliance and/or complaints about the care or use of laboratory animals. Assists with implementation of appropriate actions to enforce regulatory guidelines
- Keeps abreast of regulatory changes and evaluates policy and institute initiatives to improve the animal care and use program
- Communicates regularly with the IO, Attending Veterinarian, Animal Research Compliance Manager, and Office of Research Integrity Director
- Educates and supports IACUC members, PIs and others regarding the IACUC process
- Assists the Attending Veterinarian, Animal Research Compliance Manager, and Office of Research Integrity Director with activities that are suspended for non-compliance

IACUC Vice-Chair - The IACUC Vice-Chair serves for 3 years and then will typically take over the Chair role. The Vice Chair must also be of sufficient stature within the institution by the time the Chair role is appointed to avoid jeopardizing their position within the Institution. The Vice-Chair convenes and chairs meetings in the Chair's absence as requested.

Office of Research Integrity Director - The OFFICE OF RESEARCH INTEGRITY Director is a voting member of the IACUC and sits on all of the other research compliance committees to be well-informed of research compliance issues and research activities that may involve more than one committee. The Animal Research Compliance Manager reports directly to the OFFICE OF RESEARCH INTEGRITY Director. The Director is involved in oversight and participates in all critical IACUC functions and activities including:

- Ensures compliance with USDA and PHS regulations
- Recommends membership changes to the IO
- Reviews meeting minutes, reports, and assurances and forwards to the IO in accordance with regulatory guidelines
- Ensures that actions required in semiannual program reviews and facility inspections are addressed as soon as possible and appropriate actions are taken to address and resolve findings
- Ensures written documentation of IACUC activities is clear and communicated to all researchers, faculty, and staff
- Represents the IACUC to USDA and FDA inspectors
- Establishes a sound written communication system for the IACUC
- Participates in investigations of reports of noncompliance and/or complaints about the care or use of laboratory animals. Takes appropriate action to enforce regulatory guidelines as necessary
- Ensures IACUC information is up to date and posted on the OFFICE OF RESEARCH INTEGRITY website for the Administration, faculty, staff, and students to find easily

- Reports activities suspended by the IACUC for noncompliance to the IO

IACUC Community Member – A representative on the IACUC from the community in which an institution is located that serves as a voting member. The member’s presence on the committee fulfills more than legal requirements. The role is to question, bring ethical aspects into discussions, and support the animals’ interest. He/she must be willing to communicate what they believe would be the public’s concerns. Community members come from many different occupations and philosophical viewpoints. They may be individuals from the animal protection community, members of the religious community, lawyers, nurses, philosophers, homemakers, ranchers, farmers, public school teachers, or community veterinarians.

Pre-Review Subcommittee – The IACUC Chair assigns the Pre-Review Committee, composed of at least two voting members of the IACUC committee, the Attending Veterinarian, and the Animal Research Compliance Manager. The charge of the pre-reviewers is to make sure the protocols are ready to be sent to the full committee for review. The Animal Research Compliance Manager compiles any questions and/or required clarifications from the pre-review committee and communicates these to the PI in the form of a concerns memo. The PI must make necessary revisions to the protocol to address the pre-review concerns before the protocol will be placed on the next IACUC meeting agenda. The protocol is then distributed to all IACUC members via email for review before the next meeting. The pre-review process allows for better use of IACUC meeting time as major concerns or questions with protocols are already resolved by the time they are sent out for Full Committee review.

Principal Investigators – Only full-time UMass Lowell faculty members and qualified employees may serve as project directors/principal investigators for activities that involve animals. The PI member accepts responsibility for all aspects of the activities, even when a student conducts the work. Prior to planning or conducting an activity using animals, involved faculty, staff, and students are expected to be trained and familiar with the policies and guidelines discussed in this document. PIs are encouraged to consult with the attending veterinarian at an early stage in the preparation of protocols for activities involving animals. PIs will be held, at a minimum, responsible to

- Acknowledge and accept responsibility for the humane care and use of animals in their activity
- Comply with applicable institutional policies and governmental regulations
- Delay involvement and acquisition of animals until written approval without contingencies is received from the IACUC
- Adhere to high ethical standards
- Identify and be responsible for all personnel that will be working on the research project
- Assure that all project personnel have received adequate training to perform their duties and act in an ethical manner
- Ensure that all personnel involved with activities that involve animals are aware of medical risks and required personal protective equipment (PPE) necessary to protect both the animals and the staff handling them. The PI must ensure that all students/staff complete E&E Laboratory Safety Training, understand the importance of PPE, and that

a Medical History and Risk Assessment Questionnaire is completed for all new employees if the employee will be handling vertebrate animals

- Forward to the IACUC any proposed modification(s) to a previously approved protocol prior to initiation, and delay initiating any changes prior to receipt of written approval without contingencies from the IACUC
- Notify the IACUC of any changes in funding and submit to the IACUC a copy of the proposal submitted to request funding
- Report progress of an approved activity to the IACUC as often as, and in the manner, prescribed by the approving IACUC, but not less than one year from approval.

Students – Undergraduate and graduate student researchers must complete required training to participate in animal studies. They must be listed on a protocol to participate in a project involving animal care and use and can only be added to a protocol by the sponsoring PI. The student must adhere to all policies and procedures as approved by the IACUC.

7.0 TRAINING REQUIREMENTS

All personnel involved with the care, treatment, and or use of research animals must be adequately educated, trained, and/or qualified in basic principles of laboratory animal science to help ensure high quality science and animal well-being. The purpose of the IACUC training is to ensure all personnel involved in animal research activities understand the following key concepts:

- Proper use of materials to minimize pain and distress for the animals
- Humane animal care and use practices
- Humane euthanasia practices
- State, local, and federal regulations related to animal care and use
- IACUC Function
- Ethics of animal use
- Occupational health and safety issues and zoonosis
- Aseptic surgical techniques
- Guidelines for anesthesia, analgesia and euthanasia
- Guidelines for alternatives to animal use, methods to reducing the number of animals used, and unnecessary duplication of studies

Persons who are considered “engaged in research” include the following: principal investigators, post-doctoral candidates, research technicians, graduate and undergraduate students, and visiting scientists. All persons engaged in research must be listed on approved protocols or added through the amendment process. The IACUC considers a person to be “engaged in research” when they are:

- Assisting with data collection that involves animals used for research
- Handling animals
- Receiving Animals
- Operating equipment necessary to complete activities as approved in a protocol

Animal use protocols, annual reviews, and amendments will not be approved until the IACUC is satisfied that each person listed has a current animal users' training certification on file and is qualified to perform the procedures listed.

Training is required and will include, but not be limited to, the following:

- CITI Program certification for completion of the 'Working with the IACUC' module and training must be renewed every 3 years. Additional modules are available and may be required, depending on the nature of the research being conducted.
- Hands-on proficiency training in specific techniques including animal handling, surgery, anesthesia, blood draws, injections, necropsy training, and experimental manipulation
- Environmental Health and Safety (EHS) Department laboratory safety training
- Health and Safety Training for Animal Workers, updated annually
- Occupational Health and Safety Training
- How to report concerns for animals
- Instructions regarding animal ordering and receipt
- Information about IACUC policies and procedures

Training records are kept on file with the Animal Research Compliance Manager. Individual investigators are responsible to develop and provide training in techniques and practices for specific research activities. Information on the experience and training of each individual involved must be included on the protocol form and be officially approved in writing by the IACUC before any hands-on work may start.

Online Training Certification

Training or instruction is available to all personnel, training topics include:

- Humane animal care and use practices
- Research and/or test methods that minimize or eliminate animal use
- Research and/or test methods that limit animal pain and distress
- Database searches for alternative methods to reduce or eliminate pain and distress
- Procedures to report deficiencies in animal care and use
- Responsible conduct in research

Various other types of training are offered to all personnel on a regular basis via the following:

- Online CITI training, a certificate of completion is required to be on file before any protocol approval is granted. Certification records will be maintained by the Office of Research Integrity. Mandatory training is required to be updated every three years.
- Individual and/or group orientation sessions for newly employed personnel: Training is conducted by the Director of Research Integrity, Attending Veterinarian, the Animal Research Compliance Manager, and/or EHS personnel as needed;
- IACUC Policies and Procedures are posted online for review by all personnel working with animals. Information is also provided in regards to the process to submit protocols and IACUC meeting and review processes. In addition, Standard Operating Procedures are available to describe all routine facility processes.
- A training protocol is approved to provide standard techniques used in animal research and to allow the Animal Research Compliance Manager and/or Attending Veterinarian to oversee individual proficiencies. The hands-on instruction is provided to faculty, visiting scientists, technicians and students for specific techniques such as animal handling, surgery, anesthesia, and experimental manipulation. The IACUC requires that all personnel listed on a protocol receive appropriate procedure training or demonstrate their proficiency with specific procedures before being cleared to work with animals in the facility.
- All animal handling and procedures training follows the approved IACUC Protocol. The Animal Research Compliance Manager or Attending Veterinarian observes and declares proficiency or will conduct additional training appropriate to the needs of the researchers. An animal use protocol and annual review will not be approved until the IACUC is satisfied that each person listed on the protocol has the required animal training certification on file. Training information for each individual involved in the research must be included on the protocol and approved by the IACUC before any hands-on work may start. Records on procedure training completion will be maintained by the Animal Research Compliance Manager and records are available in the facility. Each entry will include the date of training, the procedure, and the individuals in attendance. In addition, CITI certificates of completion for the online training titled 'Working with the IACUC' will be maintained by the Animal Research Compliance

Manager and the Director of Research Integrity.

- Inviting UMass Lowell, external scientists and or USDA personnel to lecture on philosophical and technical aspects of animal research Mass Lowell

IACUC Member Training

IACUC Members are provided copies of the following resources: PHS Policy, the 2011 Guide for the Care and Use of Laboratory Animals, the Animals Welfare Act and Animals Welfare Regulations, the OLAW IACUC Guidebook and the current approved Animal Welfare Assurance. Informational items, such as regulatory updates, are routinely emailed to all Committee members. Examples of these include news briefs from OLAW and USDA updates, information on new animal models, and other relevant information on animal care and use in research. The IACUC discusses seminars and programs sponsored by other institutions or organizations. The IACUC is also informed of new OLAW guidance's and this is recorded in the meeting agenda and minutes. In addition, new members meet with the Director of Research Integrity and the Animal Research Compliance Manager to discuss protocol review, UMass Lowell IACUC Policies and Procedures, and to have an opportunity to ask questions about the responsibility.

Hands-on Training Certification

The IACUC also requires that all personnel listed on a protocol receive appropriate procedure training or demonstrate their proficiency with specific procedures before being cleared to work with animals in the facility. Personnel include faculty, post-doctoral candidates, research technicians, staff, students, and visiting scientists. All personnel are trained in the proper way of handling animals and follow specific procedural techniques when working with the animals.

The Animal Research Compliance Manager or A.V. can observe and declare proficiency or conduct training appropriate to the needs of the researchers. A training/proficiency certification form can be submitted to the Animal Research Compliance Manager or the A.V. to identify the types of procedures to be conducted and either one may verify satisfactorily demonstration of the specific procedures. The trainee must not begin any work with animals until they have received the verification from the Animal Research Compliance Manager or A. V. that they are approved to proceed with their research. Recertification for hands-on training is required at the discretion of the Animal Research Compliance Manager or A.V. Procedure training records are kept on file with the Animal Research Compliance Manager.

Additional hands-on, classroom training may also be provided by the Director of Research Integrity, the Animal Research Compliance Manager, or the AV for animal users in order to provide additional educational opportunities or to meet various federal requirements or PI needs. IACUC members (past or present) may also conduct training sessions. Individual investigators must develop and provide their own staff training in techniques and practices needed in their own laboratories.

Occupational Health and Safety Program

All personnel who work with animals or on occasion visit the animal facility are required to participate in the occupational health program. Clearance is required prior to gaining access to the facility or working with live animals. This program is intended to safeguard employees that may have sensitivity to animals and reduce liability to the University. One of the many goals

of the program is to identify persons with animal allergies and to ensure that appropriate PPE and/or equipment are used.

This plan is based on the 2011 *Guide* and the ILAR Occupational Health Guidelines. All individuals with even minimal animal contact must participate in the Occupational Health and Safety program, and thereafter, requires an annual update to renew the clearance. The program includes a tetanus vaccine or prophylaxis, health exams and other medical procedures based on risk assessment, education, and may require use of protective gear.

Persons who require a clearance must first complete a Baseline Health History Questionnaire and then an Annual Follow-up form. The user answers specific questions regarding his/her medical history and any current health issues on the form, so that a risk assessment can be performed by the EHS-contracted practitioners. Additional follow up may be required with the health care assessment team, depending upon the risks identified on the questionnaire.

Annual IACUC and Health and Safety Training

This training is provided once a year and is required to meet the OLAW Assurance requirements. This training provides an overview of health and safety risks from working with animals and informs workers how to protect themselves from injuries, allergies, and diseases. It also provides important updates to changes in IACUC policies, facility information, and reviews general safety rules and personal protective equipment for working with animals. Information is provided about how to use the Occupational Health and Safety program, contracted out through EHS with experienced physicians for all personnel who work with animals.

This training is mandatory for all researchers and students involved in the animal research. It is required for anyone who needs to continue working with animals. It also includes specific precautions for workers who may be pregnant or immunosuppressed, and reviews general safety rules and personal protective equipment for working with animals. Information is provided about how to use the Occupational Health and Safety program, contracted out through Lowell General Hospital Circle Health Occupational Medicine. In some cases, an in-person personal health care evaluation will be necessary to assess health issues from working with animals. Animal facility users are also informed of safe conduct through personal instruction and posted signs. Additional topics covered include: protective clothing requirements, use of hazardous agents, sharps disposal, bite/scratch wounds. Methods used to reduce physical injury include: provision of wheeled carts for material handling and placement of sharps containers in all sites where sharps may be used.

Personal protective equipment is provided at no cost to the user. Animal care personnel are required to wear appropriate protective clothing; shoe covers, gloves, splash goggles, respirator, safety glasses, disposable gloves, garments and hair bonnets as appropriate to safely conduct the research activity. Tyvek jumpsuits face shields, or safety goggles, and fit-tested respirators are also available for any person working in the animal facility when needed. Sinks are located in the cage wash area and in the procedure room. Sinks are equipped with anti-bacterial soap and disposable towels. No personal protective equipment shall be worn beyond the boundary of the animal facility, unless approved for special circumstances.

Laboratory Safety Training and Use of Chemicals and Biological Materials

All scientific and animal care personnel receive training in biosafety, chemical hygiene, and hazard communication. Animal studies that involve the use of hazardous substances must be reviewed and approved by the appropriate institutional safety committee(s) or Department with responsibility for oversight. The Institutional Biosafety Committee (IBC) reviews and approves projects involving biohazardous materials, infectious agents, recombinant DNA, and select agents. The Environmental Health and Safety (EHS) office reviews and approves work performed with chemical hazards. The Radiation Safety Committee reviews use of radioisotopes. Exposure control plans are in place. All scientific and personnel using such materials for animal research receive training in biosafety, chemical hygiene, and hazard communication through EHS. Animal studies that involve the use of hazardous substances must be reviewed and approved by the appropriate institutional safety committee(s).

All UMass Lowell faculty, staff, graduate students, teaching assistants, and researchers that use chemicals, generate hazardous waste, or work in laboratories are required to attend the EHS Laboratory Safety Training on an annual basis and other training as necessary specific to the research activities. (Undergraduate students are excluded from this requirement for course-related laboratory activities only.) The training is offered monthly throughout the year and the certification must be kept current to work in any UMass Lowell laboratory. The training provides information about the EHS staff and responsibilities, right-to-know law, emergency spill response notification, blood borne pathogens/biohazards, personal protective equipment (PPE), hazardous waste management, fire response procedures, and laboratory practices and policies. It is the responsibility of the faculty member or laboratory manager that oversees the laboratory to ensure that all workers have completed the EHS laboratory safety training and are certified. Training certificates are kept on file at the EHS Office.

Individuals working with radioactive materials or radiation emitting devices are required to attend radiation safety training through the Radiation Safety Office. This training is offered on an “as needed” basis and may be scheduled either through the Radiation Safety website or by calling the Radiation Safety Office. It is the responsibility of the PI to assure that all workers involved with radiation related research have completed their training prior to starting work with these sources. The Radiation Safety Office maintains the training records and will provide, at minimum, biennial radiation safety training to the radiation workers at the laboratory.

PPE is provided at no cost to the employee. Animal care personnel shall wear appropriate protective clothing, which includes shoe covers, gloves, splash goggles, safety glasses, disposable garments and hair bonnets that are required to safely conduct the research activity. No personal protective equipment worn in the facility shall be worn beyond the boundary of the hazardous work area or the animal facility. PPE is also required for handling animals in classroom and laboratory exercises that are conducted outside of the facility. Additional PPE may be required, depending on the nature of the biohazard.

8.0 REQUIRED LITERATURE SEARCH

The PHS Policy and the Animal Welfare Regulations require research institutions to ensure that PIs have considered alternatives to procedures that can cause more than slight or momentary pain or distress in animals, consistent with sound research design. It is the responsibility of the IACUC to evaluate all research protocols for the potential to cause pain or distress and to ensure steps are taken to enhance animal well-being. Each painful event should have literature search results included in this section of the protocol application. Regulations mandate that a description of **how** the lack of alternative methods was verified for each potentially painful/distressing procedure (**for Category D and/or E procedures**). The alternatives search must be in the form of a narrative description and use two databases. Alternatives that demonstrate less painful/invasive procedures should be described below. Search terms should include the name of the painful procedure together with words such as ‘**pain**’ ‘**distress**’ and ‘**alternatives**’.

Literature search documentation must include the following information:

- date the search was conducted
- procedure in question
- date range of the search
- library databases searched
- keywords used to search.

The IACUC must be able to assess whether the search topics were appropriate and whether the search was sufficiently thorough. Various databases are available depending on the type of research proposed, UMass Lowell requires at least two library database be searched. Databases available include:

Altweb, AGRICOLA, PubMed/Medline, Cambridge Scientific, TOXNET

An example narrative would include:

“On March 16 2012, a PubMed search was performed for the indicated keywords for all the listed procedures. Many of these references have validated these procedures as safe techniques in mice. Many references were redundant or irrelevant to the procedure. Although many references were found for each search, no reasonable or obvious alternatives were found”.

USDA Policies #11 and #12 include guidance for the types of procedures that are classified as D or E and requirements for conducting a search for alternatives. The IACUC strongly recommends that PIs review these policies before conducting a search for alternatives. In general, procedures that have the potential to cause pain or distress include:

- physical restraint
- survival surgeries
- food or water restriction
- death as an endpoint
- noxious stimuli
- skin or corneal irritancy testing
- tumor burdens
- intracardiac or orbital sinus blood sampling

- abnormal environmental conditions

Duplication of Research

A minimum number of animals should be used and non-animal methods be considered before any research project using animals is initiated. Alternatives suggested (from Russell and Burch 1959) include *replacement* or using non-animal models, *reduction* of numbers of animals used, and *refinement* or elimination or reduction of unnecessary pain and distress in animals. If a literature search identifies a valid alternative to the method to be used, a written narrative must be provided to explain why this alternative was not used

9.0 IACUC ADMINISTRATION AND PROTOCOL REVIEW PROCEDURES

IACUC meetings are scheduled monthly throughout the year. Meeting schedules are typically established at the end of one semester for the following semester to provide as much advance notice as possible and to secure meeting space. Meeting agendas are drafted by the Animal Research Compliance Manager and reviewed by the IACUC Chair before being sent to the committee. Under special circumstances, meetings may be held by teleconference and are coordinated and organized by the IACUC Administrator. Researchers are encouraged to attend meetings to discuss and answer any questions that may be raised by the IACUC. This helps to clarify information and also facilitate understanding for both the IACUC and the researcher. Contact the Animal Research Compliance Manager for inquiries about the meeting schedule.

Timeline for Protocol Submissions

IACUC meetings are typically scheduled monthly and the schedule is set at the end of one semester for the next semester. A PI should allow approximately six weeks from the time a protocol application is submitted for full review to receipt of a final letter of approval. It is possible that the timeline is shorter but depending on work load and committee members' schedules, six weeks should be allowed for the process.

Conflict of Interest Disclosure

A conflict of interest must be disclosed at the beginning of any meeting or before review of any documents to the Committee Chair or to the Director of Research Integrity to ensure:

- The responsible conduct and integrity of decisions made by the Committee;
- To protect the Committee membership and the University from unnecessary and avoidable litigation and;
- To ensure the committee membership complies with agreements entered into with third party funding organizations for which the committee approves facilities, protocols, activities or research projects.

The meeting agenda includes an item titled "identification of conflict of interests" and the Chair asks members present to disclose any conflict of interest. Committee members are obliged to disclose, as soon as it comes to their attention, any conflict of interest or potential conflict of interest. If a committee member is unaware of any conflict of interest or potential conflict of interest at the time they sit in a meeting in which they later discover they are in a conflict situation, they should let the Chair of the Committee or the Director of Research Integrity know immediately once the conflict comes to, or is brought to, their attention. If a committee member is in any doubt about whether or not they are in a potential conflict situation, they must state this to the committee members at the commencement of the meeting.

Clarification of Conflict of Interest

A conflict of interest is considered to be a committee member who has any of the following:

- An affiliation with any organization, company, venture or other body that involves a direct financial interest or benefit, directly or through relatives by blood or marriage, in the subject matter or materials of a protocol or registration for review by the committee;
- Direct involvement in the research subject matter under review by the committee;
- Is related, by blood or marriage, or a business partner of a person who is a researcher undertaking a protocol or registration considered by the committee;

- Is a research competitor or has a personal conflict with the project or the investigators so could be perceived as having a potential bias

Protocol Review Process

Research using animals may not be initiated until the investigator has submitted a protocol to the IACUC for review and written approval is received by the PI. The signed PI Assurance and Signature Page and training certification must also be on file before final approval is issued. To ensure prompt approval:

- Clearly and completely explain all aspects of the research
- Include study endpoints in your protocol
- Complete the database search information
- Ensure all training is completed by staff or students
- Attach required approval documents from other institutions
- Consult with the AV while planning your animal studies

All UMass Lowell animal care and use protocols are reviewed at a Full Committee IACUC Meeting and a quorum must be present. Protocols must be submitted on the most recent UMass Lowell IACUC Protocol Review Form. The process is outlined as follows:

Protocol Review by Members in the Same Department

Faculty members residing in the same Department are allowed to review protocols and materials coming from the same Department as long as the Committee member does not have a personal or financial interest in the research being proposed. If a conflict is identified, the member shall recuse themselves from participating in the discussion and vote for the research with which they have the conflict of interest. The conflicted member shall leave the room for the vote on the research, they are encouraged to provide information and answer committee members' questions prior to the vote. Recusals shall be documented in the minutes of the meeting as 'not present for the vote'. Recusals shall not count towards the quorum requirement for the review.

Pre-review

The IACUC Chair assigns the Pre-Review Committee, composed of at least two voting members of the IACUC committee, the Attending Veterinarian, and the Animal Research Compliance Manager. The charge of the pre-reviewers is to make sure the protocols are ready to be sent to the full committee for review. The Animal Research Compliance Manager compiles any questions and/or required clarifications from the pre-review committee and communicates these to the PI in the form of a concerns memo. The PI must make necessary revisions to the protocol to address the pre-review concerns before the protocol will be placed on the next IACUC meeting agenda. The protocol is then distributed to all IACUC members via email for review before the next meeting. The pre-review process allows for better use of IACUC meeting time as major concerns or questions with protocols are already resolved by the time they are sent out for Full Committee review.

Full Committee Review (FCR)

Full Committee review takes place at the IACUC meeting after the pre-review process has been completed. At the IACUC meeting, the pre-reviewers summarize questions that were raised and if and how they were resolved. The protocol is reviewed for conformance with the federal Animal Welfare Act, the Guide, and institutional regulations. Each protocol is discussed and a list of required modifications is determined, if any. A simple majority vote determines the committee's decision (see Committee Decisions) below. Dissenting views are recorded in the minutes. The Animal Research Compliance Manager and Director of Research Integrity take notes at the IACUC meeting to capture all IACUC discussions. The IACUC discussion points and concerns are then communicated to the researcher in a Memo from the Animal Care Compliance Manager to represent the IACUC. Votes and items to be revised, if any, are recorded in the meeting minutes.

Designated Member Review (DMR) for Protocols Requiring Post-Meeting Approval

The policy outlining the DMR, subsequent to FCR, process was approved by the IACUC at a convened meeting with a quorum present. The DMR subsequent to FCR process occurs when a protocol receives a vote of 'Requires Modifications to Secure Approval' after a FCR at a convened meeting and approved by the majority of the convened quorum. A vote of 'Requires Modifications to Secure Approval' indicates that the IACUC needs non-substantive modifications to the protocol before Final Approval may be given. The quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol. The protocol is sent back to the PI for revisions, the PI returns the revised protocol to the Animal Research Compliance Manager who sends the DMR subcommittee identical copies of the revised protocol for review. The DMR subcommittee can be made up of two IACUC members; designated by the Chair or by a Vice-Chair (in the Chair's absence) and additional members may be selected if deemed appropriate. The designated reviewers will have the authority to approve, require further modifications (the same) to secure approval or any member may call for Full Committee review. If the Protocol receives Final Approval through the DMR process all members must be unanimous with their decision.

Committee Decisions

All committee decisions are communicated to the PI as soon as possible after the IACUC convened meeting. The communication is in the form of a memo from the Animal Research Compliance Manager and outline specific approval, information still required, or whether the committee decided to Table the protocol.

All protocol approvals finalized after an IACUC meeting are reported on the agenda for the following meeting so that any member may raise questions about an approval if necessary. Animals may not be ordered until the protocol has received final approval and the PI has received an Approval Memo from the IACUC. The Animal Research Compliance Manager or Director of Research Integrity are the only persons authorized to approve purchase requisitions

for the purchase of animals. This practice assures that only researchers with approved protocols may acquire animals.

Approved: designates the IACUC has reviewed and approved, by the majority of the convened quorum, the protocol by Full Committee Review (FCR). Any dissenting votes are noted in the meeting minutes. The investigator is notified in writing with an Approval Letter. The Animal Research Compliance Manager must have the signed and dated PI Assurance page before the work may begin.

Requires Modifications to Secure Approval: designates that the IACUC at FCR by majority vote of the convened quorum, agreed that the protocol needs additional non-substantive clarification(s) or modification(s) to the protocol. Any dissenting votes are noted in the meeting minutes. The quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol. The investigator is notified by the Animal Research Compliance Manager in a formal memo of the modifications required. Identical copies of the revised protocol are sent to the Designated Member Reviewers who have the authority to approve, require further modifications (the same) to secure approval or any member may call for FCR. If the Protocol receives Final Approval through the DMR process all members must be unanimous with their decision. If the decision is not unanimous to approve by the DMR, the revised protocol is resubmitted and put on the agenda for FCR at the next meeting with a quorum present. The Compliance Manager issues a written memo to the PI with the outcome of the DMR process.

Tabled-Requires Significant Revisions: indicates that the IACUC has determined that the protocol is missing substantive information necessary to make a decision or a potential serious animal welfare concern has been identified at a FCR with a quorum present. The PI is notified by the Chair or the Animal Research Compliance Manager in the form of a memo and advised as to his/her options. For a tabled protocol, the PI is provided with a written outline of the problems or concerns to use as a guide for resubmission to the IACUC.

Disapproved: indicates the IACUC has determined that the research cannot be conducted at this time at a FCR with a quorum present. The investigator is provided with a memo outlining the reasons for the IACUC decision.

Investigator Notification

The researchers (PI) are notified of the IACUC decision in writing as soon as possible after the meeting, regardless of the outcome of the review.

Final Approval

Final approval to move ahead with the project is granted when written IACUC approval is sent to the PI by the Animal Research Compliance Manager.

Protocol approval is for three years, contingent upon satisfactory annual review of the project. Protocols for which an Annual Review has not been filed are not approved to

continue and must cease all activities. For PI record keeping, all approval letters list the Annual Review and 3-Year Renewal dates.

Amendments

A protocol amendment must be filed whenever a previously approved animal use protocol requires modification. This process must be followed any time changes are requested. Do not postpone reporting changes until the annual review. Any and all animal procedures, manipulations, and actions **must be** noted on an amendment, reviewed by the IACUC, and approved by the IACUC **prior** to instituting any of the modifications. Contact the Animal Research Compliance Manager to initiate the amendment as the experimental plan is formulated. The requested amendment must fit with the objectives, purpose or aims stated in the *original* protocol. If this requirement is not met, the IACUC will require submission of a new protocol. Only PIs may submit an amendment.

Minor

The following types of changes to approved protocols are submitted on the Minor Amendment Form:

- Small change in animal numbers (< **10%** of the previously approved number for mice and Rodents or non-traditional species only *(Note: For teaching activities under an approved protocol, a minor amendment is allowed for an increase in animal numbers even if >10% providing the justification is an increase in class size.)*)
- Change in acclimation period
- Change in diet
- Change in housing
- Change in strain of animal species
- Change in sex of animal to be used
- Change in age of animal to be used
- Change in title
- Change of faculty collaborator
- Change of student or technician
- Change in a procedure that is **less invasive** than the approved protocol
- Transfer of animals to another PI where the same stock/strain are already approved on that study

Minor amendments may be approved by the IACUC Chair, their designee, or the IACUC Attending Veterinarian. Allow approximately 10 working days for approval. The review process is as follows:

- Amendment is reviewed and additional information may be requested
- Upon approval, an official copy of each minor amendment will be emailed back to the PI with who approved the amendment and the date of approval. An original will be placed in the protocol file. **No work may be initiated until the approved version is received by the PI.**
- All minor amendments are reported to the IACUC at the next scheduled meeting, and may be revisited by the IACUC if any member determines this appropriate.
- A minor amendment may be determined to be major depending on the information contained in the description.

Major Amendments

If the proposed changes are significant, a Major Amendment form must be completed to include all of the required information, all Major Amendments require FCR. Review of the amendment is handled as explained in Part III.D.6 above. The following changes are considered to be a Major Amendment:

- Study objectives are different
- Surgery becomes non-survival to survival
- Procedures are more invasive than initially proposed
- Increased pain, discomfort, or distress to animal
- Increased proportion of expected animal deaths
- Change or addition of a species
- Anesthetic agents
- Hazardous agents will be administered to animals
- Use or withholding of analgesia
- Increased duration, frequency of number of procedures performed
- Change in PI
- Change method of euthanasia
- Change in number of animals (>10% of the original approved request)

Major Amendments require full IACUC approval and the form should be submitted to the Animal Research Compliance Manager at least 15 working days prior to the next scheduled IACUC meeting date and before the PI needs the amendment to go into effect. A preliminary review will be performed by the IACUC Pre-Review Committee. If the IACUC decides to withhold approval of a proposed major amendment, the PI will receive written notification that includes justification for withholding approval. The PI may then address the IACUC concerns in person or in writing and the IACUC may reconsider in light of additional information provided by the PI. Committee approval of all amendments will be documented in the IACUC minutes.

Annual Reviews and Renewals

The IACUC procedures for conducting continuing review are to mandate annual renewal of all protocols. The Animal Research Compliance Manager reminds the PI to complete an **Annual Protocol Review & Continuation Form** one month before the approval anniversary date at the end of the first and second year. If significant changes are proposed, the PI is informed that he/she is required to submit a major amendment outlining the changes. The following information must be completed by the PI for the Annual Review to reflect what occurred during the previous year:

- Species and number of animals used, number of animals that remain to be used,
- Significant proposed changes such as increase in numbers; change in species, strain, study goals, surgical or non-surgical procedures, or agents and biohazardous materials being administered to animals
- Proposed changes to personnel working under the protocol
- Adverse events
- Future activities

While protocols are initially approved for 3 years, the protocol must still be renewed

annually. At the 3-year anniversary, a new protocol application must be submitted for a *de novo* review and include all previous modifications or amendments made to the original protocol. The triennial renewal is treated as a new application and is reviewed by Full Committee Review as described previously.

If the annual renewal form and/or triennial renewal application is not submitted before the expiration date, approval of the protocol lapses and animals may no longer be used or ordered for that research project. All animals are placed on a Holding Protocol until full approval is secured.

Termination or Closing IACUC Protocols

A protocol is automatically terminated after three years. A protocol is also terminated if no annual report is received by the IACUC on or before the anniversary of the protocol approval date. The investigator may terminate a project at any time by notifying the IACUC by email that the project is completed. Please notify the Animal Research Compliance Manager as soon as your project is completed to keep records up to date. When a project is completed or a protocol expires, all animal use on that protocol must stop. No further purchase of animals can be made under the specified protocol number. The PI, AV, and Animal Research Compliance Manager will receive official notice of the termination. Access to existing study animals on the terminated protocol will not be permitted. Terminated protocols records are held in the Office of Research Integrity for a 3-year period from date of closure.

Holding Protocols

For situations that require suspension and animals remain in the vivarium, to avoid euthanasia of those animals and to remain in compliance with regulatory requirements, the IACUC allows the transfer of animals to a holding protocol for a maximum of 60 days. During this time, the investigators are asked to take the necessary actions to gain re-approval of their animal use protocol in order to avoid forfeiture of their animals. Use of the Holding Protocol (HP) is intended to be temporary.

No experimental procedures are allowed on animals maintained on the holding protocol. Any use of animals for research purposes while on the holding protocol will be treated as serious regulatory noncompliance. Breeding may be performed only to maintain viability of specific lines occurring under this protocol. Breeding to expand a colony is not authorized. Feeding, sanitation and environmental enrichment will be performed as expected for the species. Husbandry duties may be performed by the Animal Care staff, the PI or previously approved and qualified personnel.

Holding Protocols

Holding Protocols may also be used for other situations which may include:

- Animals ordered without an approved protocol (noncompliance situation).
- Animals originating from inactive (or terminated) protocols.
- Animals on a protocol under investigation for potential issues of noncompliance where the welfare or wellbeing of the animals is in question.
- New investigators without an IACUC-approved protocol having animals that may require immediate housing at UMass Lowell.
- Investigators that are leaving UMass Lowell and do not have approval for transfer to the new institution.

- Animal Care staff is only authorized to transfer animals on a holding protocol to another PI after consultation with the original PI. Request forms to place animals on the UMass Lowell holding protocol must be completed by the PI, the IACUC Chair, or the Attending Veterinarian (AV). PIs will submit the form to the AV or the IACUC chair either of whom can authorize the transfer of animals from an active protocol to the holding protocol. All actions will be reported to the IACUC at the next regularly scheduled meeting.

Per diems for animals will be charged to the investigator (or department) while animals are on the holding protocol. No animal related costs may be charged to federal funding sources until the three-year renewal is approved by the IACUC.

Expired Protocols or Late Annual/Triennial Reviews

All animals at UMass Lowell used in research or teaching must be held or used under an approved protocol. If animals are in-house under an expiring protocol, and the PI fails to transfer them to the holding protocol, the AV or designee must transfer the animals to the UMass Lowell holding protocol five business days prior to expiration.

If the Annual/Triennial Review is not conducted within one year or three years respectively of initial approval, the protocol is considered expired and animals must be transferred to the holding protocol until the Annual/Triennial Review is approved.

Appeal of an IACUC Decision

If a PI wishes to appeal an IACUC decision, it must be done so in writing to the IACUC Chair, who will bring it to the next scheduled meeting for review. The PI will be informed in writing of the outcome within five working days of the IACUC meeting at which it was reviewed. The IACUC decision regarding an appeal is final. The IO is not authorized to overturn IACUC decisions.

10.0 MISCELLANEOUS INFORMATION

General

Prior to any acquisition or use of animals, each individual proposing to conduct an animal activity must submit a completed Protocol Review Form to the IACUC. Any change to an existing protocol is considered an amendment and must also be submitted to the IACUC for review, **including changes in funding for previously approved protocols**. (Refer to the Amendments section for more information.) Any protocol or amendment must be formally approved by the IACUC before any work with animals can be initiated. A written memo or letter of approval to the PI from the IACUC indicates that the project is ready to begin.

Only UMass Lowell permanent faculty or qualified staff members may be listed as a PI on an animal use protocol. Students may help to prepare a protocol but the signatory authority and responsible party must be a faculty member. The PI has final responsibility for oversight of any project involving animals, even if it is a student project. Protocol Review Forms, for training purposes are completed by the Animal Research Compliance Manager, to provide hands-on training to faculty, staff, technicians, and students.

Accidents and Injuries and Reporting Requirements

All accidents and injuries (including animal bites and needle sticks) must be reported immediately to the Animal Research Compliance Manager. An emergency phone extension 42911 has been established and is staffed 24 hours a day in the University Police Office, University Crossing for medical emergency response by UMass Lowell Police and EMTs. Upon notification to University Police regarding an injury, the dispatcher answering the phone will call for medical assistance and an ambulance, if necessary. The injured person and Animal Research Compliance Manager are to reference the University's Blood Borne Pathogen Program and Exposure Control Plan to assure that appropriate "Post Exposure and Follow-Up" procedures are followed. The student is then referred to the Health Services Department for follow up treatment.

Animal Blood and Tissue Use

If animals are euthanized for a research project for the purpose of obtaining the blood or tissue, an IACUC protocol is required. IACUC approval is not required if tissue collection takes place postmortem as a by-product of a commercial enterprise, like a slaughterhouse. IACUC approval is not required for the harvest of tissues from dead animals from other research projects as long as the collection of tissues does not alter the approved procedures in any way and the animals were used exclusively for the other research project.

PIs should be aware that if the "use of vertebrate animals" box is not checked on the face page of a PHS grant application form, references to the use of animals in the grant proposal may trigger questions about IACUC approval. To avoid delays in peer review of a proposal, the PI is advised to explain in the grant application the source of the tissues.

PIs interested in sharing blood and tissues from animals euthanized after a project is completed should network to maximize the use of such materials, while ensuring that all EHS policies are met regarding such substances.

Animals from Non-Approved Sources

Animals may not be brought to campus to the main animal facility from a non-approved source as there is a chance the animal is harboring infectious disease(s) even though it may appear healthy. Non-approved sources of animals include wild-caught animals and animals from non-approved animal vendors or other institutions. Animals requested from non-approved vendors will need to be quarantined at an off-site facility that can manage such animals for at least eight weeks. Researchers are required to pay for any quarantine costs. Animals may not be used for research projects until they are cleared from quarantine. Animals must have a recent documented health screening from the place held for quarantine for review by the UMass Lowell AV prior to being shipped to UMass Lowell after the quarantine period. Breeding is not allowed for animals in quarantine.

Antibody Production Protocols

Protocols that involve antibody production is not allowed at this time at UMass Lowell.

Categories of Animal Use Subject to IACUC Review

The IACUC reviews all research projects, sponsored or unsponsored, involving the use of living non-human vertebrate animals, or animals euthanized for the purposes of the study, to ensure the humane care and use of animals including, but not limited to, the following:

- Faculty or staff research projects
- Graduate student projects
- Undergraduate student honor projects
- University-approved research by investigators not affiliated with the university who propose to involve university students, staff, or faculty in a proposed research project

Collaborations and Use of Animals at Other Facilities

Research collaborations involving UMass Lowell faculty, staff or students and other institutions using laboratory animals must be reviewed by the UMass Lowell IACUC, whether funded or not. If the funding for the project flows through UMass Lowell, the UMass Lowell IACUC will be the responsible IACUC and review the proposed activities. For PHS-funded projects the Office of Laboratory Animal Welfare (OLAW) at NIH requires that the host institution has either an "Assurance" or a "Foreign Assurance" approved by OLAW. If the collaborating institution does not already have an OLAW Assurance, it will need to obtain one and this may be a lengthy process. The project may begin only after IACUC approval.

If animal research activities involving UMass Lowell personnel are conducted at domestic or foreign sites other than UMass Lowell, the IACUC must be satisfied that PHS policies are being followed. The IACUC, at its discretion and depending on the nature of the study and the roles of UMass Lowell personnel in the study, may choose one of three options to ensure appropriate oversight of the project:

- Accept the collaborating institution's IACUC approval, especially if that institution holds a current OLAW Assurance or is AAALAC certified.
- Conduct the review of the protocol submitted to the UMass Lowell IACUC in the host institution's protocol format.
- Conduct a review of the research submitted on the UMass Lowell protocol form.

In any case, the UMass Lowell IACUC needs to review documentation from the collaborating institution that verifies IACUC review and approval of the project before the UMass Lowell IACUC issues final approval for the UMass Lowell Investigator to proceed.

Communication

Communication among all the people involved in animal care and use is vital to keep everyone informed and in compliance with UMass Lowell policies and procedures. PIs must be notified for various reasons about policy and regulatory changes, the status of applications or amendments, the condition of their research animals, or issues with their students, technicians, or staff. A designated representative must be listed on the protocol application form as well as email addresses of all parties involved in the project. The purpose of a designated representative is to identify someone involved in the project that is authorized to make a decision should the PI not be available.

All parties listed on a protocol should be included for all communication related to it so that all parties are aware of the status of the project and the likelihood of violations is reduced. The contact list should always include the PI, co-PI, designated representative, students, staff, and technicians listed on the protocol or amendments and the Animal Research Compliance Manager, IACUC Chair, and AV. This will help resolve questions or alleviate problems that need to be addressed quickly that can arise from miscommunication. For example, when an animal is in distress and action needs to be taken, the PI and all other contacts provided on the protocol or amendment will be contacted to notify them of the condition of the animal and provide them with 24 hours to address the problem. After 24 hours, the IACUC Chair, AV, or their designee will authorize the Animal Research Compliance Manager to euthanize the animal if the PI or their designated contact has not responded. The cadaver of the animal in question will be refrigerated to allow the PI to collect any tissue at a later date.

The PI must read and approve all communications sent to IACUC prior to review by the IACUC. Often amendments are written by students or technicians. Communication among the entire group ensures that the PI sees all correspondence and is aware of any proposed changes to a protocol. An approval will not be issued until the Animal Research Compliance Manager or Chair receives the appropriate documentation from the PI. This record verifies to the IACUC that the PI is aware of and approves all amendments and procedural changes.

Field Studies

Because UMass Lowell is covered by an Animal Welfare Assurance it must comply with PHS Policy. PHS Policy does not distinguish between field and laboratory studies and covers all vertebrate animals. Therefore, before a field study can start, the PI must submit

a Protocol Review Form for IACUC review and approval. All personnel listed on a field study protocol must complete training for researchers who work with wildlife.

Sponsored Research Activities

PIs that seek external funding for activities involving animals should coordinate the timing of the submission of the Protocol Review Form to the IACUC with the sponsor's application deadline. Some sponsors require IACUC approval at the time of proposal submission. Remember to allow six weeks from the time the application is submitted to full approval. A copy of the proposal submitted for funding that involve animal research must also be submitted to the IACUC for review by at least one person (IACUC Chair, Animal Research Compliance Manager, or Attending Veterinarian) to insure consistency with proposed activities and IACUC-approved protocols.

Ordering Animals

A current IACUC approved protocol or amendment is required before animals can be purchased or housed. Animals may not be ordered until the protocol has received final approval and the PI has received an Approval Memo from the IACUC. The Animal Research Compliance Manager or Chair are the only persons authorized to submit and approve purchase requisitions for the purchase of animals. This practice assures that only researchers with approved protocols may acquire animals. Contact the Animal Research Compliance Manager to coordinate procurement to order animals and arrange for housing.

Photographing Animals

Photography is allowed with prior IACUC approval only. Appropriate handling and restraint methods for the species must be used and procedures described in the protocol. No references to personal or institutional information should be visible in the photograph. Animals should be in clean surroundings, clean cages, or clean pens and water bottles and feeders should be visible in the photograph if applicable. No animals that are ill or have visible lesions or alterations are to be photographed without specific permission from the AV, PI or IACUC Chair. If the purpose is to disseminate research results, then appropriate care should be taken to drape the animal and if possible show only the area of interest in the photograph. Cell phones are restricted from use in the facility to prevent unauthorized photography. Incoming calls may be received outside of the facility.

Use of Animal Images for Non-Research Purposes

The use of photographs, videotapes, or other types of animal images for purposes other than scientific research (e.g., recruiting, website information, documentaries) must be submitted to and approved by the Vice Provost for Research and the Chief Public Affairs Officer as the use of such photographs or images could impact the public reputation of the university. Since the use of images for the purpose of public relations types of activities is outside of the IACUC responsibility of assuring ethical use of animals in research, UMass Lowell Administration will be responsible to approve these types of activities. Notification of the administrative decision will be sent to the PI and copied to the Animal Research Compliance Manager and IACUC Chair.

Planning Your Project

Prior to any acquisition or use of animals, each individual proposing to conduct activities using animals must submit to the IACUC a completed Protocol Review Form. Animal

users are strongly encouraged to seek assistance from the Attending Veterinarian during the planning stages prior to submission of the application especially to obtain specific information related to drugs to alleviate pain and distress or surgical procedures. This will help to streamline the process and reduce frustration for all parties involved. Federal guidelines require documentation that reduction, replacement, and refinement options have been addressed and the AV can also assist you with that process. While planning the project allow sufficient time for the IACUC to complete the process. The completed protocol review form is first reviewed by the pre-review committee and questions are directed back to the PI to clarify any unclear or questionable information. Then the revised protocol is submitted to the full IACUC for review and discussion. To facilitate the process, check with EHS staff for use of chemicals, the Institutional Biosafety Committee for use of biological agents, and/or the Radiation Safety Officer for using radiological agents. A separate form and review process may be necessary if your project involves various types of hazardous materials.

Release of Protocol Information

Information on protocols is released only to the PI or co-PI listed on the protocol, the Institutional Official, animal care staff with valid reason, IACUC members, Animal Research Compliance Manager, and authorized regulatory or accreditation site visitors.

Teaching Activities

It is the policy of University of Massachusetts at Lowell that the use of live vertebrate animals solely for instructional purposes is NOT generally permitted.

Courses Using Animal Materials and Student Notifications

Academic departments and programs should alert prospective students of any courses required for a major or degree that involve the use of animal materials. This requirement may be met by a statement to the effect that 'some required courses for certain degrees may involve use of animal tissue and students should seek further information about such requirements or alterations to meet the course requirement from the Department'.

Instructors should inform students during the first week of class if animal tissues will or may be used as part of that course. Students who have concerns about the use of these materials may then choose whether or not to take the class. Students should feel free to discuss their concerns with the instructor, but should be aware that instructors and departments are not obligated to alter course requirements that are consistent with University policies.

Student Research Projects

All graduate student research is overseen by a faculty advisor, who also serves as the Principal Investigator (PI) on any graduate research project using animals. The student may not initiate any research using animals until all training is completed and the protocol has been reviewed and approved by the UMass Lowell IACUC. It is recommended that the graduate student be closely involved in the preparation of the protocol but the PI has final responsibility for the project. Allow approximately six weeks from the time of initial submission for review and final approval of a project using animals.

Animal Research at Other Institutions and Coordinating IACUC Approval

If the research using animals will be conducted at another institution, the PI should inquire whether the other institution has an IACUC. If it does, the research activities must first be approved by that institution's IACUC. The PI should then submit the other institution's approved protocol as well as their approval documentation (letter, memo, etc.) to the UMass Lowell IACUC for review. Approval by the UMass Lowell IACUC will be contingent upon receipt of approval documentation. For research conducted at another institution, it may take approximately three months for protocol approval. The UMass Lowell IACUC reserves the right to withhold its own approval pending satisfactory responses to any questions resulting from a review of the other institution's protocol. The research may not proceed without documented approval from both IACUCs. If the other institution has no IACUC, the project must be reviewed and approved by the UMass Lowell IACUC but see below if the project is funded by a federal Public Health Service (PHS) agency.

For projects conducted at another institution **and** funded by a PHS agency (e.g. NIH): the institution with which a collaborative study is planned **must** have an Assurance Statement on file with the Office of Laboratory Animal Welfare (OLAW) of NIH. This is a federal requirement for any collaborative study involving Public Health Service funding and applies to vendors and commercial collaborators as well as academic institutions. For PHS-funded international collaborations conducted at a foreign institution the host foreign institution needs a "Foreign Assurance" approved by OLAW.

Visitor Policy

No person may enter an animal facility without appropriate authorization from the IACUC Chair or Animal Research Compliance Manager. Authorization must be requested and approved prior to any visit. In addition, visitors must be accompanied at all times by a UMass Lowell full-time faculty or staff. This is, in part, to prevent transmission of any pathogens to the UMass Lowell facility should someone visit more than one animal facility on the same day, and to ensure that all visiting personnel are performing business directly relevant to research being conducted by faculty in the facility or affiliated with UMass Lowell administration. If you have any questions or seek visit authorizations, please contact the Compliance Manager.

11.0 TRANSPORTATION OF RESEARCH ANIMALS

The Guide for the Care and Use of Animals 8th Edition (the Guide) states:

“Animal transportation may be intra-institutional, inter-institutional or between a commercial or non-commercial source and a research facility. For wildlife, transportation may occur between the capture site and field holding facilities. Careful planning for all types of transportation should occur to ensure animal safety and well-being. The process of transportation should provide an appropriate level of animal biosecurity while minimizing zoonotic risks, protecting against environmental extremes, avoiding overcrowding, providing for animal physical, physiologic or behavioral needs and comfort, and protecting the animals and personnel from physical trauma. Movement of animals within or between sites or institutions should be planned and coordinated by responsible and well-trained persons at the sending and receiving sites to minimize animal transit time or delays in receipt. Defining and delegating this responsibility to the appropriate persons, who are knowledgeable about the needs of the species being shipped, will help ensure effective communication and planning of animal transport. For non-commercial sources of animals, in particular, it is important for the veterinarian or the veterinarian’s designee to review the health status and other housing and husbandry requirements prior to authorizing shipment of animals. This will ensure that effective quarantine practices are implemented for incoming animals as well as addressing any special requirements needed to ensure animal well-being”.

General UMass Lowell IACUC Policies on Laboratory Animal Transportation

- The performance site for all animal procedures must be described in the IACUC Protocol and reviewed and approved by the IACUC
- Methods for transporting animals to and from transport sites must be reviewed and approved by the IACUC unless from UMass Lowell approved commercial vendor (e.g. Charles River Laboratories, Jackson Laboratories)
- All personnel assisting in transport must be listed on the approved IACUC protocol
- An Animal Transport Request Form must be completed and submitted to the ORS Facility Manager if transporting animals out of Olsen 618

Guidelines for Transporting Animals Within a Building

- A cart must be used for transporting 3 or more cages and cages should never be stacked
- The cages and cart must be completely shielded from public view by use of a drape or other covering (Note: yellow gowns are not appropriate as they are transparent)

Guidelines for Transporting Animals Between Buildings

Transporting rodents in personal vehicles is not recommended, if proposed the procedure must be described in the IACUC protocol and approved by the IACUC

- Standard cages must be placed inside of a secondary container with a secure lid, the container must be opaque and withstand sanitization
- The transport vehicle as well as the transport site must provide adequate heating/cooling to maintain general animal comfort
- The secondary container must be placed inside the vehicle, never in the trunk or truck bed and must be secured to the inside of the vehicle to prevent movement (e.g. bungee cord)
- Animals should be protected from direct sunlight and public view
- Animals must be transported directly to the other building -no stops should be made

Guidelines for Transporting Animals to Another Institution

- Approval from the other institution must be obtained from the UMass Lowell Animal Research Compliance Manager prior to scheduling transport of the animals to another institution
- Animals transported to another institution and returning to UMass Lowell will require IACUC Approval from both institutions. If **PHS funds** are involved the performance site may be deemed a satellite facility and therefore included on the UMass Lowell. Semi-Annual Facility Inspection schedule
- Animals transported to another institution and not returning to UMass Lowell will require approval from the both Attending Veterinarians
- Primary and secondary enclosures, as described above, must be used
- The transport vehicle as well as the transport site must provide adequate heating/cooling to maintain general animal comfort, temperatures must be monitored while in transit as well as at transport site
- The secondary container must be placed inside the vehicle, never in the trunk or truck bed and must be secured to the inside of the vehicle to prevent movement (e.g. bungee cord)
- Animals should be protected from direct sunlight and public view
- If stops are necessary, animals must never be left unattended in the car for more than a few minutes

Use of Non-Research Bred Animals for Research

Animals for research that are not obtained from vendors who commonly provide animals for research-bred purposes are regulated and controlled by the U.S. Fish and Wildlife Service (USFWS). USFWS authority is provided under the Endangered Species Act (ESA) and the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). USFWS covers the importation, exportation, and interstate trade of all dead and live wild animals and their tissues and products imported into or exported from the United States for any purpose, including research. Permits are required in order to use these species for scientific purposes, to operate a captive-breeding program, and to transport these species through importation, exportation, or interstate trade. Applications generally require 60-90 days for processing.

USFWS defines wildlife as any wild animal, whether alive or dead, including any wild mammal, bird, reptile, amphibian, fish, mollusk (clam, snail, squid, or octopus), crustacean (crab, lobster, or crayfish), insect, sponges, corals, or other invertebrate, whether or not bred, hatched, or born in captivity and including any part, product (including manufactured products and processed food products), egg, or offspring thereof. In some instances, a single FWS application may be used to obtain permits under both programs, though not all species listed under ESA are CITES listed species and vice versa.

Transportation Guidelines for Live Non-Research Bred Animals

Live Animal Regulations provide guidelines for air transportation companies that are members of International Air Transport Association (IATA). Persons or organizations that ship live animals by IATA-member airlines, whether as cargo or as baggage, must comply with the regulations in their entirety. The regulations are intended to prevent harm to the containers and

to handling personnel when animals are being transported in addition to meeting flight safety requirements for the benefit of the traveling public, the crew, and the airplane.

Transportation or Shipping of Live Animals from Non-Approved Vendors by Air or Land

(This includes shipment of all reptiles and amphibians)

The PI is responsible for maintaining all records that cover shipping, importing or exporting animals and have ready all such materials for inspection by the IACUC upon request. The following information must be provided to the IACUC by the PI:

- Name of the shipping company(s) used for each shipment and their code of practice for animal transportation including practices for boxing and containment and husbandry requirements including substrate, food and water, stocking densities
- Environmental conditions requested during shipment
- Information regarding essential notifications and communication regarding shipments and deliveries
- Estimated schedule for shipment and delivery and who will be available for receipt of animals
- All necessary documentation (including licenses and labels as necessary)
- Description of the quality and quantity of substrate, nesting material, food and water required during transport.
- Emergency procedures and contacts for UMass Lowell personnel

The shipper must provide the following documentation to the IACUC **before** animals are ordered for an approved protocol:

- Container type used for the shipment and labeling information. Include information about the type and quantity of substrate, nesting material, food and water provided during transport, if any. If none is provided, please state.
- Statement from the shipper that they will following all guidelines to meet IATA standards for shipping
- If more than one company is involved in the transport, all carriers should be listed in the protocol and all carriers will need to provide verification that they also follow IATA standards
- Verification that all vehicles are environmentally controlled for all segments of ground transportation
- If environmentally controlled vehicles will not be used, or air travel is involved, contingency plans for maintenance of the animals if the ambient temperature is below or exceeds acceptable ranges.
- Statement outlining the acceptable temperature ranges for when animals may be shipped.
- Verification that the shipping company has standard operating procedures for ensuring that animals are not exposed to extreme environmental conditions during transfer between vehicles and at the end destination.
- The expected duration of the journey;
- The number of stops or changes between planes or vehicles, especially if unloading and reloading is required

- Type(s) of vehicle(s) involved in transportation Information regarding vehicle cleaning, vehicle maintenance and routine maintenance checks
- Expected estimated duration of the journey and approximate delivery date and time.
- Statement regarding the experience and training for all personnel handling and transporting the animals, including subcontractors.
- Details about how the animals will be acclimated from the journey and how they will be monitored when they reach their destination.

Contact Information for Approved Shipping Vendors

World Courier Ground Inc.

125 Whipple Street 2nd Floor, Providence, RI 02908

TransporTech, LLC

1041 Pearl Street, Unit H, Brockton, MA 02301

12.0 SATELLITE FACILITIES

The IACUC policy attempts to centralize animal facilities as much as possible, but in some circumstances, it may be necessary to establish a decentralized facility. Approval to establish a decentralized facility will only be allowed with adequate justification. Such facilities must be constructed to meet the standards outlined in the *Guide for the Care and Use of Laboratory Animals (8th edition Guide)*, federal law, and current institutional policies.

The process of approving such a facility may take several months. The IACUC and AV should be consulted periodically during the planning process to avoid costly mistakes and delays in approval of the facility. Once the facility is completed, the IACUC schedules an inspection and uses the facility inspection guidelines to document any deficiencies. Deficiencies are formally communicated in writing to the PI. The deficiencies must be addressed and/or corrected before a follow up IACUC inspection is conducted. Once the IACUC approves the facility, a written approval notice is sent to the PI. Animals may only be procured after the facility is inspected and approved for animal use.

It is the PI's responsibility to ensure that all federal and institutional regulations are implemented and followed. This includes the care and use of all animals, seven days a week, including weekends and holidays. The PI must ensure that all personnel involved in animal handling are properly trained in animal care and use and have completed the required UMass Lowell training modules. Veterinary and IACUC Compliance oversight continue as if the animals were in the central facility. Failure to meet required expectations may result in the loss of the privilege to have a decentralized facility.

The Animal Research Compliance Manager will visit the facility periodically during the initial operations to make certain standard operating procedures are in place and being followed. Per diems will be charged based on the animals housed and the intensity of involvement required by the IACUC and Animal Research Compliance Manager. Once it is clear that the personnel responsible for management of the new facility understand and are following the SOPs, then frequency of visits by the Animal Research Compliance Manager are reduced. The Animal Research Compliance Manager is available upon request for weekend or holiday assistance with the daily health checks. Fees for weekend health checks to satellite facilities are outlined in the UMass Lowell per diem rate schedule.

The IACUC may also check periodically to make sure that SOPs are being followed, and that the maintenance of the facility, husbandry practice, and animal care are in line with those of the centralized facility in Olsen Hall. The daily health checks are the responsibility of the decentralized facility personnel and those personnel should be identified and coordinated to operate the facility in the absence of the PI. These person(s) are required to have the appropriate training on animal handling and clinical observation, as well as knowledge regarding emergency procedures in case there are issues with the facility and/or animals. Semi-annual facility inspections are conducted by the IACUC and the PI will be notified as to the dates of the inspections. All deficiencies noted in semi-annual inspections are communicated in writing to the PI and must be addressed as soon as possible in accordance with UMass Lowell policies and regulatory guidelines (see the section in this document on USDA Inspections & Semi-annual Reviews).

13.0 REPORTING CONCERNS & PROTOCOL NONCOMPLIANCE

Several options are available for reporting concerns regarding animal care and use and are outlined in the annual training. Any employee, student, or agent of UMass Lowell reporting a concern will be protected against reprisal. Every effort will be made to protect the complainant's confidentiality, but UMass Lowell is an agency of the Commonwealth of Massachusetts and is therefore subject to the Massachusetts Public Records law, G.L. c.66, § 10. This law states the general rule that any record made or received by an officer of the Commonwealth is presumed to be a public record and must be released to "any person" who requests it. If appropriate, concerns involving the care and use of animals may fall under the purview of the UMass Lowell Policy on Misconduct in Science.

"Whistleblower Policy" that includes procedures for individuals to use in reporting concerns to the IACUC and for the IACUC to use in evaluating those concerns and providing protection against reprisal as required by the Animal Welfare Act. Any concerns are reported to the Institutional Official. The policy is posted in the animal facilities. In addition, a Compliance Hotline has been established to receive anonymous complaints that are available to all University faculty, staff and students. Detailed information (see below) about the types of reports and protections for 'whistleblowers' is posted on the Office of Research Integrity website, and included as part of the mandatory training to be taken by all investigators and their staff annually. Any reported issues will be addressed immediately and appropriate solutions will be determined on a case-by-case basis by the IACUC. This is managed through an investigation conducted by the IACUC, typically in the form of a subcommittee, with presentation of the findings to the IACUC at a convened meeting with a quorum of members present. The IACUC discusses the findings and determines the appropriate course of action in consultation with the Institutional Official. The IACUC's decisions and actions are reported in the minutes of its meetings.

Several options are available for reporting concerns regarding animal care and use and are outlined in the annual training. Any employee, student, or agent of UMass Lowell reporting a concern will be protected against reprisal.

Concerns may be reported in any of the following ways:

- A Compliance Hotline has been established at 978-934-3100 to provide a means to anonymously report potential compliance violations or suspected wrongdoing.
- Visit the UMass Lowell Office of Research Integrity at 215 Wannalancit at 600 Suffolk Street.
- Call the Director of Research Integrity
- Write up a memo and title it "Confidential Report of Concern" and put in intercampus mail or regular mail to the Director of Research Integrity at 215 Wannalancit, 600 Suffolk Street, Lowell, MA 01854.

Initial information to be obtained from a complainant includes:

- Complainant's name (optional)
- Nature of the concern(s)
- Description of the event or charge and the observed date of the alleged violation(s)

- Copies of any written, photographic, or taped documentation to substantiate the complaint
- Names of other people who may corroborate the complainant's concerns

The Director of Research Integrity, IACUC Chair, Animal Research Compliance Manager will review the information and consult with other committee members to determine the seriousness of the complaint. If an investigation is necessary, the IACUC may obtain additional information through:

- Unannounced visits to the location of the concern (laboratory/facility)
- Review of laboratory procedures, IACUC protocols, lab/facility documents (including records pertaining to animal purchase, care, health records, or research records)
- Interview with the Principal Investigator (PI)
- Interviews with laboratory personnel, co-workers, etc.
- Letters or interviews with other individuals who might provide information for the investigation
- Assistance from other IACUC members in collection of information

The IO is informed immediately if animal or human welfare is at risk. A plan of action and completion date is determined, and the necessary individuals are assigned tasks to resolve the situation. If an activity is suspended, OLAW is notified by the IACUC through the IO.

IACUC Policy on Noncompliance

The IACUC must review and if warranted, investigate concerns involving the care and use of animals. All complaints must be reviewed but not all complaints may need to be investigated. Protocol noncompliance occurs when procedures or policies affecting animal care or use are not followed. When faced with protocol noncompliance, the IACUC will work to bring the protocol into compliance or take immediate action to stop any mistreatment of animals. The IACUC is empowered to make a decision as to the type of violation and suspend any research or teaching activity if it finds violations that are a threat to the health or safety of animals or activities conducted that are not in accordance with provision of the AWA, the Guide, or the UMass Lowell Assurance (PHS Policy IV,C,6 and IV,C,1,a-IV,1g). The IACUC as a full committee may suspend activity and/or make a decision as to the type of disciplinary action recommended and make such recommendations or consult with the IO to impose further sanctions. The AV also has the authority to suspend an activity to provide adequate veterinary care and the IACUC will be quickly notified to review the decision. The IACUC is empowered by the UMass Lowell Chancellor, who has appoints the IO. Frequent communication is encouraged between PIs, Director of Research Integrity, IACUC Chair and Compliance Manager to avoid compliance issues.

Deviations from IACUC policies are reported to the IACUC Chair, Director of Research Integrity, and the IO. If there is a deviation from the UMass Lowell policies and procedures, an IACUC meeting will be convened, members informed of the complaint/investigation, and a decision about appropriate action will be made. If the IACUC determines that the violation is valid, the PI, department chair, college dean and/or IO will be notified of the IACUC's recommendations or action. If the individual reporting the concern is dissatisfied with the IACUC's decision, concerns may then be presented to

the IO but the IO cannot override an IACUC decision. For Public Health Service funded research, the IO is required to report serious or continuing non-compliance with the PHS policy, any serious deviations from the provisions of the Guide, and any suspension of a research activity to the PHS Office of Laboratory Animal Welfare (OLAW). Regardless of the funding source, the IO must notify the USDA of any suspensions of activities involving USDA covered species. USDA typically communicates this information to PHS. Failure to comply with the Animal Welfare Act can carry penalties that range from a reprimand to the levy of a substantial fine, along with the immediate suspension of all activities associated with the use of animals by the individual investigator, or by the entire institution. These regulations are not subject to negotiation or individual interpretation by investigators.

Any and all violations require prompt response to resolve the problem that initiated the violation. All incidents are entered into the animal care log and reported to the IACUC Chair and IACUC Administrator. Specific information about minor and major violations and a guideline of typical IACUC responses are provided below. The IACUC has the authority to determine violations more serious than those outlined here and take necessary steps to meet the requirements of the Animal Welfare Act. Actions that may necessitate stronger levels of enforcement by the IACUC include transmission of infection or disease into the facility or compromising human health as a result of ignoring policies and procedures.

Minor Violations

Minor violations are situations in which the UMass Lowell Policies and Procedures are not followed but there is no immediate harm to the animals. Warnings and minor violations will be entered into the animal care log, reported at the next IACUC meeting, and entered into the meeting minutes. The ORS Manager is held responsible to notify the IACUC Chair and Animal Research Compliance Manager about the incident and if possible recommend corrective action.

Examples of minor violations might include improper entry into animal quarters, failure to adhere to ORS SOPs, improper waste disposal, failure to clean or maintain an area, improper disposal of dead animals, improper maintenance, incomplete cage cards, using expired food, not wearing proper PPE, failure to maintain or falsifying daily records, or improper ordering procedures. Any member of the IACUC may call for full IACUC review of a minor violation and discussion of corrective actions at a meeting. Response to a minor violation is outlined as follows:

First Minor Violation:

- Written notification is sent to the PI
- Immediate action is taken to resolve the problem
- Follow-up review is conducted by the Director of Research Integrity

Second Minor Violation:

- Written notification is sent to the PI and Department Chair
- Immediate action is taken to resolve the problem

- PIs and staff are required to retrain on the procedure or review the SOP that was violated
- Follow-up review is conducted by the Director of Research Integrity

Third Minor Violation

- Written notification is sent to the PI and Department Chair
- Immediate action is taken to resolve the problem
- PI and staff are required to retrain on the procedure or review the SOP that was violated
- Follow-up review is conducted by the Director of Research Integrity
- PI is required to attend an IACUC meeting

Major Violations

Major violations are situations in which the UMass Lowell Policies and Procedures are not followed and there is immediate harm to the animals. When it appears that procedures involving live animals are being conducted without prior IACUC approval, health and safety of personnel is threatened, or animals are used in violation of regulatory guidelines, the AV has the authority to suspend the activities and the IACUC must convene as soon as possible thereafter to vote on immediate cessation of the activity pending completion of the investigation. Any activities that are suspended are required to be reported to the IO and the PHS or USDA. Actions will be taken as expeditiously as possible to obtain an appropriate resolution.

Examples of major violations might include repeated minor violations, use of animals without an IACUC approved protocol or amendment, using non-approved anesthesia or euthanasia, disregard for animal suffering, having more than the accepted number of animals per cage, conducting research without the proper training, or knowingly providing false or inaccurate information to the Animal Research Compliance Manager or IACUC. Response to a major violation is outlined as follows:

First Major Violation:

- PI is informed, project activity is suspended, and the violation is corrected immediately
- Person committing the violation and the PI must be retrained from a second on-line course and submit certificates of completion to the Director of Research Integrity
- IO is informed and notifies PHS and/or USDA
- Further activity on study in question is suspended until above conditions are met
- Follow-up review is conducted by Director of Research Integrity to assure continued compliance

Second Major Violation:

- PI and Department Chair are informed, project activity is suspended, and violation is corrected immediately
- Person committing the violation and the PI must be retrained from a second on-line course and submit certificates of completion to the Director of Research Integrity
- IO is informed, notifies PHS and/or USDA, and determines whether the funding agency is notified of the violation
- All further activity involving animal use is suspended for 30 days.

- PI is required to meet with the IACUC
- After suspension requirement is met, a follow-up review with the Director of Research Integrity is conducted before any animal use can resume

Third Major Violation:

- PI and Department Chair are notified, project activity is suspended, and the violation is corrected immediately
- Person committing the violation and the PI are retrained from a second on-line course and must submit certificates of completion to the Director of Research Integrity
- IO is informed, notifies PHS and/or USDA, and determines whether the funding agency is notified of the violation
- PI is required to meet with the IACUC and the IO
- All further activity involving animal use is suspended for 90 days or longer and the University Ethics Committee (established under the Misconduct in Science Policy) is contacted to evaluate the situation as an ethics violation

Disciplinary Actions

Typical disciplinary actions are outlined above for minor and major violations. Depending on the severity of the violation, enforcement or disciplinary actions may also include but not be limited to termination of privileges, suspension of privileges, probation, a letter of reprimand, mandatory training, or other actions deemed necessary by the IACUC or IO.

14.0 USDA INSPECTIONS & SEMIANNUAL REVIEWS

The OLAW Assurance requires that all animal care facilities be inspected and the IACUC program review be conducted by the IACUC at six-month intervals. IACUC evaluations are based on the NIH Guide for the Care and Use of Laboratory Animals, Animal Welfare Regulations, and Office of Laboratory Animal Welfare (OLAW). Inspections are also conducted at least annually by the USDA.

USDA Inspection

The Animal Welfare Act (9CFR part 2.38b) allows the Animal and Plant Health Inspection Service of the USDA (APHIS) to access and inspect the records, facilities, property, and animals of animal research facilities. APHIS officials conduct unannounced inspections as necessary to enforce the provisions of the Animal Welfare Act. At the end of an inspection the USDA inspector details his/her findings via a report. The report gives a deadline for addressing areas of non-compliance. Research Compliance Manager distributes the inspection report as soon as possible after receipt to the IO, IACUC Chair, the IACUC members, and the Director of Research Integrity. The IACUC Chair reviews the inspection report and assigns each non-compliant item listed to one or more responsible persons or units, such as the study PI, Research Compliance Manager, Department Head, or the IACUC. The IACUC Chair may request a corrective action plan within a specified time period and completion date which will be reviewed by the IACUC. Following the date of completion, the Director of Research Integrity or designee will inspect to verify that the corrective action plan is in place and working. The Director of Research Integrity may also make unannounced inspections of the laboratory facility.

Semiannual Program Review

The semiannual program review is conducted at least once every six months by the IACUC. An OLAW checklist is provided as a guideline for reviewing the Institution's program for the humane care and use of animals. The checklist covers the requirements of PHS Policy and major topics of the Guide including Institutional Policies and Responsibilities, Veterinary Care, Training, and Occupational Health and Safety. Under each key function, specific points are then rated to indicate whether the IACUC program is acceptable, has a minor deficiency, or significant deficiency in that subject area. A summary sheet notes the date the review is conducted, the members in attendance, whether it is a minor or significant and repeated deficiency, plan for correction, responsible party, and schedule to correct the deficiency, and the date it is completed. This review is retained by the IACUC Administrator, a copy is sent to the IO, and is provided by request to any regulatory authority.

Semiannual Facility Inspection

The OLAW Assurance requires that a facility inspection be conducted twice per year by the IACUC. As well as the animal use facilities, drugs, materials intended for in vivo use, surgical logs, and animal care records are inspected. During the inspection process, a checklist is completed, and the IACUC determines whether the finding is a minor or major deficiency. At the conclusion of the inspections, the IACUC Administrator prepares a Semiannual Inspection Report which is reviewed by the IACUC. Depending on the findings in the report, the IACUC Chair may assign deficiencies listed to one or more

responsible persons or units, such as the study PI, Research Compliance Manager, Department Head and/or the IACUC. The IACUC Chair will request a corrective action plan within a specified time period and a completion date which will be reviewed by the IACUC. Following the date of completion, the Director of Research Integrity will inspect to verify that the corrective action plan is in place and working.

All surgical areas in animal care facilities and survival surgery areas in investigator's laboratory are included in the inspections. This includes areas in laboratories where survival surgery on rodents is practiced in order to maintain compliance with, and meet the spirit of, the AWAR, PHS Policy and Guide (both the AWAR and the Guide detail facility and procedural requirements for conducting survival surgery on rodents or APHIS/AC covered species). The IACUC attempts to inspect sites that include housing enclosures. When review of such sites is not feasible, the IACUC may request that photographs, videos and husbandry SOPs be submitted for review.

Deficiencies

There are two possible types of deficiencies; Significant and Minor. Deficiencies can be related to either a protocol or the facility. Significant deficiencies are those in which there is a threat to the health or safety of the animals. A minor deficiency is one which does not threaten the health or safety of any animals. For both types, a plan must be developed with a schedule for correcting each deficiency. A re-inspection is also scheduled to ensure the deficiency has been resolved. The inspection report is included in the annual file of laboratory inspections, placed in the PI's protocol file if required, and recorded in the IACUC meeting minutes. If an acceptable action plan cannot be worked out with the PI he/she will be asked to meet with an IACUC subcommittee to review the deficiency and develop an action plan.

For a significant deficiency, prompt corrective action must be taken to address and resolve the situation. For certain deficiencies, a temporary "quick fix" is acceptable to protect the animals while planning and implementing a final, long-term solution. The IACUC Inspection Subcommittee works with the PI/Office of Research Services Manager to immediately correct the deficiency and/or develop an action plan. The IACUC Chair will, if the situation warrants it, call an emergency meeting of the IACUC to review the situation. Alternatively, IACUC members are informed of the investigation via email. Members vote to approve/disapprove the action plan. The investigators work with the primary investigator/facility to implement the approved action plan to prevent further threat to the health or safety of the research animals. The investigators keep the IACUC informed of progress. If a special IACUC meeting is not convened at the time of the complaint, investigation findings and the action plan are formally presented at the next convened IACUC meeting.

If the site manager is unwilling to correct a significant deficiency and refuses to work with the IACUC Inspectors, the inspectors immediately report this to the IACUC Chair and Director of Research Integrity. The Chair convenes a meeting of the IACUC to review the facts and vote on whether the research in the laboratory must cease (non-compliance hold or suspension) or can continue. A vote for suspension must be by a majority of the IACUC members present. A quorum (50% plus one) of the IACUC votes on the action plan. Once the IACUC has voted to put a hold on or suspend research because of a significant deficiency, the PI must assure the

IACUC in writing that a plan is in place to prevent the deficiency from reoccurring following correction of the deficiency and before any projects involving the use of animals can resume.

15.0 USE OF HAZARDOUS MATERIALS AND ANIMAL RESEARCH

Hazardous materials may be used for different aspects of animal research. To ensure that there is oversight for these types of materials, the IACUC includes as members the Director of Radiation Safety, an E&E Department Safety Specialist, and an Institutional Biosafety Committee member. This makes certain that UMass Lowell policies and procedures and federal, state, and local regulatory guidelines are followed at all times. Projects may include materials that are biological, radiological, or chemical in nature. When these materials are required, special approval by the appropriate oversight committee may be required before IACUC approval is granted.

Biological Agents

Use of any biological or biohazardous agents in animals, including recombinant DNA, is limited to activities which can be safely carried out with consideration for the available laboratory facilities and personnel training. All projects that involve biological-originated materials are reviewed by the Institutional Biosafety Committee (IBC) and must be approved by the IBC before final IACUC approval is granted. For assistance evaluating materials to be used with animals for research, contact the Biosafety Specialist.

Radiological Agents

The UMass Lowell Radiation Safety Office, concurrently with the IACUC animal welfare review, evaluates personnel safety, training, and procedures for animal studies using radioactive materials or radiation emitting devices. Any project using radiation emitting devices or radioactive materials must be approved by the Radiation Safety Committee prior to starting the project. The Radiation Safety Office's mandate is to ensure that individuals using radioactive materials have appropriate safety training and that they use, store, and dispose of the radioactive material in accordance with regulations. The procurement, use, and disposal of radiological materials shall be coordinated through the Radiation Safety Office in accordance with the applicable federal, state, and municipal regulations. Anyone interested in performing animal experiments using radioactive materials must 1) register and undergo general radiation safety training with the Radiation Safety Office at UMass Lowell, and 2) have their laboratory registered with the Radiation Safety Office for compliance. Information on the UMass Lowell Radiation Safety Program may be found in the UMMASS LOWELL Radiation Safety Guide or by contacting a member of the Radiation Safety Office.

Chemical Materials

Use of any hazardous materials (toxic chemicals or drugs) in animals is limited to activities which can be safely carried out given the available facilities and personnel training. The Environmental & Emergency Management Department (E&E) reviews and approves of the use of any hazardous chemicals. Use and handling of hazardous chemicals must be cleared with the E&E Department. For more information, contact the E&E Department or the Office of Research Integrity or visit their websites. Training requirements are outlined in a previous section of this document. Investigators using hazardous agents in animals must have knowledge in the use of the hazardous material in accordance with the Material Safety Data Sheet (MSDS), federal and state regulations, and UMass Lowell E&E policies. Hazardous Materials and Right to Know training is required by Massachusetts

law before working with hazardous materials. Hazardous agents include might include carcinogens. Contact the E&E Department for a training schedule and other information about the proposed material. Before a project involving hazardous materials is approved, the IACUC requires review of the project by appropriate E&E personnel for management of the material to prevent exposure of the investigators, animal care, and veterinary staff and to prevent release of any hazardous agent into the environment. Employees involved with or who may face potential exposure to hazardous materials must undergo training by E&E or the principal investigator to understand proper laboratory practices and potential health concerns from working with such substances. Vaccinations and/or health screening may be necessary before, during, and/or after employee involvement in such activities.

16.0 APPENDIX

A. Forms

- Animal Care and Use Protocol Review Form
- Minor Amendment Form
- Protocol Annual Renewal Form
- Baseline Health Questionnaire
- Follow-up Health Questionnaire for Persons Handling Animals

B. References

- Animal Welfare Act and Animal Welfare Regulations.
- Institute for Laboratory Animal Research, National Research Council. 1996. *Guide for the Care and Use of Laboratory Animals*. National Academy Press, Washington, DC.
- Code of Federal Regulations, Title 9, Chapter 1, Subchapter A – Animal Welfare, Parts 1 to 4.
- The IACUC Handbook. 2000. Edited by J. Silverman, M.A. Suckow, and S. Murthy. CRC Press, Boca Raton, FL.
- Institutional Animal Care and Use Committee Guidebook. 2nd Ed. 2002. Applied Research Ethics National Association and Office of Laboratory Animal Welfare.
- Code of Federal Regulations. 1985. Title 9 (Animals and Animal Products), Subchapter A (Animal Welfare). Washington, D.C.: Office of the Federal Register.
- Public Health Service. *Policy on Humane Care and Use of Laboratory Animals*. 1996, revised August 2002. OLAW, National Institutes of Health. Bethesda, MD.
- Institute for Laboratory Animal Research, National Research Council. *Occupational Health and Safety in the Care and Use of Research Animals*. 1997. National Academy Press, Washington, D.C.
- Podolsky, M.L, and V.S. Lukas, editors. 1999. *The Care and Feeding of an IACUC*. CRC Press, Boca Raton, FL.
- USDA-APHIS Animal Care Policy Manual.
- Health Research Extension Act of 1985 (P.L. 99-158), November 20, 1985-Animals in Research.
- Silverman, J., Suckow, M.A. & Sreekant, M. editors. 2000. *The IACUC Handbook*. CRC Press, Boca Raton, FL.
- Interagency Research Animal Committee. U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (Office of Science and Technology Policy, Washington, DC, 1985). <http://fmp-8.cit.nih.gov/oacu/guidepi/references/2govprinciple.pdf>
- AVMA Guidelines for the Euthanasia of Animals: 2013 Edition **C. Training**

Resources

- AAALAC International
- American Association for Laboratory Animal Science
- Animal Welfare Information Center

- Informational Resources for Institutional Animal Care and Use Committees. 1985 – 1999, AWIC Resource Series No. 7.
- IACUC 101. Sponsored by the Office of Laboratory Animal Welfare in conjunction with other partners.
- IACUC.ORG
- OLAW's PHS Policy Tutorial
- Collaborative Institutional Training Initiative (CITI)