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Policies and Procedures for the Humane Care and Use of Animals

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UNIVERSITY OF MAINE

POLICIES AND PROCEDURES FOR THE

HUMANE CARE AND USE OF ANIMALS

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I. Definitions

- A. "Animal" means, for the purposes of this policy, any live, vertebrate, non-human animal used or intended for use in research, teaching, biological testing, or related purposes.
- B. "Animal facility" means any building, room, area, enclosure, or vehicle, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.
- C. "Assurance" means the Animal Welfare Assurance submitted by the University to the U.S. Department of Health and Human Services, National Institutes of Health, Office of Laboratory Animal Welfare.
- D. *Guide* means the Public Health Service *Guide for the Care and Use of Laboratory Animals*, Eighth Edition or succeeding revised editions.
- E. USDA APHIS stands for the United States Department of Agriculture Animal and Plant Health Inspection Service.
- F. OLAW stands for the Office of Laboratory Animal Welfare. They provide guidance of the Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals.
- G. Animal Welfare Regulations (AWRs) are the regulations from the USDA related to the Animal Welfare Act.
- H. IACUC (Institutional Animal Care and Use Committee) is the Committee appointed to oversee the animal program at the University of Maine.

II. Preamble

The University of Maine is committed to the ethical principles stated in this preamble concerning the use of live vertebrate animals for research, teaching, or testing. These principles shall guide all persons associated with the University of Maine.

Vertebrate animals may share in varying degree many sensory, emotional, and cognitive responses with humankind. It is essential that we assume responsibility

for their welfare and that animal use for research or teaching purposes be conducted in a humane, compassionate manner.

To justify the ethical costs of using live animals in research, teaching, or testing, there must be reasonable expectation that such usage will contribute to the advancement of knowledge which may eventually benefit humankind and/or animals.

The University of Maine accepts and incorporates into the policy and code of ethics: (1) the National Institutes of Health *Guide for the Care and Use of Laboratory Animals*, (2) the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching*, and (3) applicable government regulations.

III. Policies

- A. The University of Maine acknowledges and accepts responsibility for the ethical care and use of live vertebrate animals.
- B. The University shall maintain and support an Institutional Animal Care and Use Committee (IACUC), whose function it is to determine whether and how live animals may be used in research, teaching, and testing, and to educate the community with regard to the ethical use of animals.
- C. No research, teaching, or testing activities using live vertebrate animals shall be initiated until the IACUC has approved a protocol for such use. Before such approval is granted, proper consideration shall be given to the degree of pain and stress to the animals, the anticipated benefits of the proposed use, and the importance of the knowledge that may result from that use.
- D. Researchers and instructors shall abide by the humanitarian dictum that animals not be subjected to unnecessary pain or distress.
- E. The IACUC shall generally consider animal welfare of greater importance than issues of experimental expense or inconvenience.
- F. If pain or distress are necessary concomitants of an approved experiment, they shall be minimized both in intensity and in duration. In no case shall pain result in suffering.

- G. If the withholding of food and water is necessary to an approved experiment, it shall be as short-term as possible and result in the least detrimental effect on the health of the animal.
- H. Prolonged physical restraint procedures are prohibited. Short-term physical restraint procedures may be approved only after alternative procedures have been considered and found to be inadequate.
- I. Multiple major surgical procedures on a single animal are discouraged, except when they are interrelated and essential to the primary surgical objectives.
- J. Potentially painful experiments, otherwise consistent with these policies, may be approved provided the animal is anaesthetized and insensitive to pain during the entire procedure, unless justified (in writing) for scientific reasons.
- K. An animal that is observed to be in a state of severe pain which cannot be alleviated, or an anaesthetized animal that would be in such a state if allowed to regain consciousness, shall be immediately euthanized using a humane, acceptable method which must include as an initial action, in the case of still conscious animals, rapid inducement of unconsciousness.
- L. Experiments involving the use of tumors or toxic or infectious agents shall be designed, whenever possible, with an endpoint other than death caused by the treatment. As soon as the experimental endpoint has been reached, diseased animals should be humanely euthanized.
- M. Each investigator shall consider alternatives to the use of live animals in research before presenting a protocol for the use of live animals.
- N. Live animals shall be used for teaching and demonstration purposes only to achieve specific instructional objectives which cannot be achieved through available alternative methods, such as the use of videotapes, films, or computer models.
- O. The responsible faculty member shall provide sufficient supervisory staff per student to achieve the instructional objectives and to assure the humane use of the animals involved.
- P. The responsible faculty member shall use the fewest animals possible, consistent with the instructional and research objectives. Permission to use more animals may be granted if they are subsequently to be used as food.

- Q. Hands-on surgical procedures shall not be taught to students whose educational needs and/or long-term professional aspirations will not normally require such experience with live vertebrates.
- R. If the instructional procedures will cause pain or distress, the same guidelines governing research with live animals shall apply also to their use in teaching and demonstration.
- S. The University's policies and procedures for the humane care and use of animals shall apply to all research, teaching, and testing activities which make use of live vertebrate animals *and*:
 - 1. are sponsored by the University; *or*
 - 2. are conducted by or under the direction of any faculty, staff member, or student of the University in connection with his or her institutional responsibilities; *or*
 - 3. are conducted by or under the direction of any faculty, staff member, or student of the University using any property or facility of the University.
- T. The University of Maine shall encourage and promote constructive communication among research administrators, department chairs, deans and directors, investigators, instructors, staff, and students as a means of maintaining a high level of awareness regarding the humane care and use of live vertebrate animals.
- U. The University of Maine shall comply with all federal, state, and local regulations pertaining to the humane care and use of animals.

IV. Procedures

A. Responsibilities of the Investigator or Instructor

The individual faculty, staff, or student of the University who uses animals for research, teaching, testing, or related purposes shall exercise the following responsibilities:

- 1. The investigator or instructor shall abide by the humanitarian dictum that animals not be subjected to unnecessary pain or stress.

2. The investigator or instructor shall design and present first to the department chair (or appropriate unit director) and then to the IACUC a protocol for the proposed care and use of animals.
3. The investigator or instructor shall not initiate any activity using animals without the prior approval of the IACUC.
4. The investigator or instructor shall make no significant alterations to the approved protocol without the prior approval of such alterations by the IACUC.
5. The investigator or instructor shall report at once to the IACUC any unanticipated harm to animals.
6. The investigator or instructor shall report annually to the IACUC on the conduct of approved projects using animals and shall seek approval for continuation of such use at least once every three years, and more frequently if the IACUC so requires.
7. The investigator or instructor shall cooperate fully with the IACUC in monitoring the care and use of animals.
8. The investigator shall ensure that they and their staff are abiding by the *Guide*, federal, state, and local laws and regulations and institutional policies that apply to the use of animals in research or teaching.

B. *Responsibilities of the Department Chair or Unit Director*

The chair of any department or director of any other unit in which animals are used for research, teaching, testing, or related purposes shall exercise the following responsibilities:

1. The chair or director shall assure compliance with the University's policies and procedures for the humane care and use of animals in the activities conducted within the department or other unit.
2. The chair or director shall assure proper management of the animal facilities within the department or other unit and proper supervision of the animal care personnel.

3. The chair or director shall nominate from among the members of the unit who use live vertebrate animals a representative to serve on the IACUC.

C. *The Institutional Animal Care and Use Committee*

1. *Responsibilities*

The Institutional Animal Care and Use Committee (IACUC) shall exercise the following responsibilities:

- a. The IACUC shall review at least once every six months the University's program for humane care and use of animals, using the *Guide* as a basis for evaluation.
- b. The IACUC shall inspect at least once every six months the University's animal facilities (including satellite facilities), using the *Guide* or the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching* as a basis for evaluation.
- c. The IACUC shall prepare reports of the evaluations required above and submit the reports to the Institutional Official for Animal Welfare.
- d. The IACUC shall review concerns about the care and use of animals at the University brought to its attention by any member of the community.
- e. The IACUC shall make recommendations to the Institutional Official for Animal Welfare regarding any aspect of the University's animal program, facilities, or personnel training.
- f. The IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of activities related to the care and use of animals in research, teaching, or testing.
- g. The IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes in previously approved

activities related to the care and use of animals in ongoing research, teaching, or testing.

- h. The IACUC shall devise and conduct programs of education in matters relevant to the care and use of animals for the benefit of students and employees of the University.
- i. The IACUC shall maintain records of its activities.

2. *Authority*

The IACUC is authorized to:

- a. Approve, disapprove, or require modifications (to secure approval) in the protocols submitted to it.
- b. Monitor the care and use it has approved by any means it deems appropriate.
- c. Suspend or terminate approved use of animals whenever such use is not being made in accordance with the IACUC's requirements or whenever it has been associated with unexpected harm to animals.
- d. Inspect animal facilities (including satellite facilities) at any time and without prior notice.

3. *Membership*

The IACUC in consultation with the Office of Research Compliance shall nominate and the President (or designee) of the University shall appoint members of the IACUC to three-year terms. Members may be reappointed to further terms. The President (or designee) may also appoint alternates when desirable. Such alternates shall have the same voting privileges as the member for whom they substitute.

The President (or designee) of the University shall appoint one member of the IACUC to serve as Chair for a term of two years. The Chair may be reappointed to further terms. The Chair shall normally be a member of the University's tenured faculty who engages in research or teaching with animals and who has substantial experience in the review of research and teaching with

animals. The President (or designee) will also appoint one IACUC member to serve as a Vice-Chair for a two-year term. The Vice-Chair may be reappointed to further terms.

The IACUC shall have no fewer than seven members, qualified through their combined experience and expertise to oversee the University's animal program, facilities, and procedures. In addition to possessing the professional competence necessary to review specific activities, the IACUC shall be able to ascertain the acceptability of proposed animal use in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IACUC shall therefore include persons knowledgeable in these areas or have access to the counsel of such persons. No department may have more than 3 members on the IACUC.

The IACUC shall include at least:

- a. One Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the University.
- b. One practicing scientist experienced in research involving animals.
- c. One member whose primary concerns are in a nonscientific area, such as an ethicist, a lawyer, or a member of the clergy.
- d. One individual who is not affiliated with the University in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the University.
- e. The Biosafety Officer (BSO) for the University and a member of the Department of Safety Management (SM) shall be appointed to the IACUC as non-voting, ex officio member(s) of the IACUC.

An individual who meets the requirements of more than one of these categories may fulfill more than one requirement. However,

the IACUC may not consist of fewer than seven members. No member of the IACUC may participate in the IACUC's review or approval of any project in which the member has a conflicting interest, except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.

The IACUC may, at its discretion, invite individual' with competence in special areas to assist in the review of complex issues. These consultants may not approve or withhold approval of an activity or vote with the IACUC.

4. *Functions and Operations*

The Chair shall convene monthly meetings of the IACUC for the purpose of reviewing protocols for approval of the use of animals in research, teaching, or testing. Except when a designated member review (DMR) is used, the IACUC shall review proposed protocols only at such meetings. Because members of the IACUC need to study protocols before the convened meeting, the IACUC shall normally consider only those that have been submitted at least two weeks prior to the meeting. In acting on protocols for approval of animal use, the IACUC shall follow the written procedures outlined in this document.

A quorum consisting of the majority of the membership shall be necessary for action on protocols. Approval of a protocol shall require the approval of a majority of the members present at the meeting.

At least once every six months, the IACUC shall appoint a subcommittee of at least two members to inspect and evaluate each animal facility. Using the *Guide* or the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Training* as a basis, the subcommittee shall evaluate both the physical plant and the animal husbandry associated with each facility. The findings and recommendations of the subcommittees shall be reported to the Institutional Official for Animal Welfare.

At least once every six months, the IACUC shall review the University's program for the care and use of animals, including (in addition to animal husbandry and physical facilities), these policies

and procedures, veterinary care, the qualifications of personnel responsible for animal care and use, training programs, and measures related to personal hygiene and occupational health for employees and students working with animals. In addition, the evaluation will include a review of the Institution's Public Health Service (PHS) Assurance. Its findings and recommendations shall be reported to the Institutional Official for Animal Welfare.

5. *Review of Protocols*

In order to approve proposed projects or proposed significant changes in ongoing projects, the IACUC shall conduct a review of those components related to the care and use of animals and determine that the proposed projects are in accordance with University policy. In making this determination, the IACUC shall confirm that the project will be conducted in accordance with the Animal Welfare Act insofar as it applies to the project, and that the project is consistent with the *Guide* unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the project conforms with the University's Assurance and meets the following requirements:

- a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research or instructional design.
- b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator or instructor. Any such experiment will require a consultation with the Attending Veterinarian. Please also see the [USDA pain classification \(Word\)](#) for definitions and examples.
- c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly and humanely euthanized at the end of the procedure or, if appropriate, during the procedure.
- d. The living conditions of animals will be appropriate for their species and maintain their health and comfort. The

housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.

- e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
- f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
- g. Methods of euthanasia used will be consistent with the recommendations of the [American Veterinary Medical Association Panel on Euthanasia \(2020\)](#), and other standard references, unless a deviation is justified for scientific reasons in writing by the investigator or instructor.

Protocols for approval of the use of animals shall be prepared by the principal investigator or instructor and submitted to the IACUC, via the Office of Research Compliance using the protocol review form found on the [IACUC website](#). Copies of project protocols shall be provided to each member prior to the review meeting.

When a protocol undergoes a full committee review (FCR) and modifications are required to secure approval, a designated member review (DMR) may be used. The DMR will typically be conducted by the IACUC Chair. The IACUC Chair may seek the assistance of the Institutional Veterinarian, or any other IACUC member he/she deems necessary to evaluate the revised protocol.

All IACUC members must agree (in advance and in writing) that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. Any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

In some special circumstances, where a protocol or amendment requires review outside of the normally scheduled IACUC meeting dates, a DMR may be conducted by one IACUC member. If the

protocol or amendment involves significant pain or distress, DMR may be conducted by three members of the IACUC, following initial consultation with the Institutional Veterinarian. Prior to final protocol approval via DMR, each IACUC member will be provided with a copy of the protocol, and a polling procedure will be used to determine whether all members of the IACUC are in agreement that the protocol or amendment is suitable for approval via DMR. Consent to approve DMR is obtained by direct vote or assumed based on silent assent after five (5) working days. Objection by any voting member of the IACUC results in the protocol being scheduled for FCR.

In the event that a DMR is conducted by more than one IACUC member, all DMR member reviewers must either approve or require (the same) modifications (to secure approval); failing either, they must submit the protocol for FCR. If modifications are required to secure approval, all members of the DMR will review the revised protocol for approval. Decisions on reviews conducted by the DMR, including requested modifications, are maintained and recorded in the minutes of the next convened meeting of the full IACUC.

No member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum. The IACUC may invite consultants to assist in reviewing complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.

Protocols receiving IACUC approval may be subject to further administrative review by the Institutional Official for Animal Welfare or by another officer of the University appointed to that purpose by the President of the University. This review may result in limitations and restrictions on the use of animals beyond that required by the IACUC. In extreme cases, the use of animals may be denied. Under no circumstances can the administration approve a project not approved by the IACUC or ease any restrictions imposed by the IACUC.

The IACUC shall notify investigators and instructors in writing of its decision to approve or withhold approval of activities related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator or instructor an opportunity to respond in person or in writing.

The IACUC shall conduct continuing review of activities covered by these policies at appropriate intervals as determined by the IACUC, but at least once every three years.

All materials provided to the IACUC for review and meetings discussions must be kept confidential.

6. *Exemption from IACUC Review*

Activities involving the use of tissues and cells obtained from an outside source from an already euthanized animal may be exempt from IACUC review. The investigator should still submit an email to the Office of Research Compliance (umric@maine.edu) with a brief description of how the tissues will be obtained, how they will be used, and the sponsor of the activity (if applicable). The investigator should also maintain records on how the tissues were procured.

Please note that if the tissues are to be acquired from animals **specifically purchased or euthanized for the activity** then IACUC review is **required**.

7. *Closing a Protocol*

Approved protocols are active for 3 years. Pilot studies are approved for 1 year. The Principal Investigator may close a protocol at any time by notifying the Office of Research Compliance.

If a Principal Investigator is leaving UMaine, the protocol must be closed or a new PI must be assigned to the protocol and approved by the IACUC. Arrangements must be made for the transfer or disposition of animals left on protocols. 60 days prior to departure, the PI should begin planning for the disposition of the animals. If

the animals are being transferred, the PI should contact the Facility Manager where the animals are housed and contact the Attending Veterinarian to make the appropriate arrangements.

The Office of Research Compliance may close a protocol if the PI fails to submit an annual renewal form.

8. *Suspension and Termination of Animal Use*

The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the *Guide*, the University's Assurance, or the *Public Health Service Policy on Humane Care and Use of Laboratory Animals*. Failure to follow the experimental procedures outlined in the IACUC protocol can also result in suspension or termination of the IACUC approval. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with a vote for suspension by a majority of the quorum present.

If the IACUC suspends an activity involving animals, the Institutional Official for Animal Welfare in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation, in writing to the Office of Laboratory Animal Welfare. If required, any extramural agency sponsoring the activity will also be notified.

9. *Recordkeeping Requirements*

The IACUC shall maintain:

- a. minutes of its meetings, including records of attendance, activities of the committee, and committee deliberations;
- b. records of protocols, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld;
- c. records of semiannual IACUC reports and recommendations, including minority views, as forwarded to the Institutional Official for Animal Welfare; and

- d. records of the qualifications of those certified to care for and use animals in University activities.

All records shall be maintained for at least three years; records that relate directly to protocols, proposals, and proposed significant changes in ongoing activities reviewed and approved by the IACUC shall be maintained for the duration of the activity and for an additional three years after completion of the activity. All records shall be accessible for inspection and copying, at reasonable times and in a reasonable manner, by members of the IACUC, by representatives of governmental agencies responsible for regulating research with animals, by representatives of extramural sponsors of University activities involving animals, and by any other person so authorized by the President of the University or by the Institutional Official for Animal Welfare.

10. *Reporting Requirements*

The IACUC shall report to the Institutional Official for Animal Welfare the actions it takes on all protocols for approval of activities involving animals, and to the Office of Research Administration all actions pertaining to activities supported by extramural funding or proposed for such support.

The IACUC shall report to the Institutional Official for Animal Welfare at once any action to suspend or terminate approved activities, and any serious or continuing non-compliance by University personnel with the IACUC's requirements and determinations. The IACUC shall provide through the Institutional Official for Animal Welfare to the Office of Laboratory Animal Welfare of the National Institutes of Health a full explanation of the circumstances and actions taken with respect to any serious or continuing noncompliance with these policies, any serious deviations from the provisions of the *Guide*, or any suspension of an activity by the IACUC.

The IACUC shall report through the Institutional Official for Animal Welfare to the Office of Laboratory Animal Welfare at least annually:

- a. any change in the University's program or facilities which would place the University in a different category than specified in its Assurance;
- b. any change in the description of the University's program for animal care and use;
- c. any changes in the IACUC membership; and
- d. notice of the dates that the IACUC conducted its semiannual evaluations of the University's program and facilities.

Reports filed under these requirements shall include any minority views filed by members of the IACUC.

The IACUC must complete a report annually to the USDA. The report includes the species and number of animals per species involved in IACUC approved activities. The report also includes the number of animals used in each pain category during the reporting period.

If a protocol supported by PHS funds is terminated or suspended, the Institutional Official must report this to OLAW. If a protocol with a USDA covered species is suspended, a report must be submitted to the USDA.

D. *Occupational Health and Safety Program*

The IACUC works closely with the Institution's Occupational Health and Safety Program. All animal care protocols submitted for review by the IACUC include a risk assessment questionnaire to provide ongoing review of safety concerns. The University's Occupational Health and Safety Program (for all personnel working in laboratory animal facilities or have frequent contact with animals) is as follows:

The Department of Safety Management is responsible for the overall management and monitoring of the Occupational Health and Safety Program.

The Occupational Health and Safety Program is administered through the Department of Human Resources (HR). In most cases, the hiring department, the Safety Management Department (SM), and a UMaine

Healthcare Provider will be involved in conducting and evaluating the risk assessment. Human Resources will communicate with the employee regarding the need to schedule medical follow-up. When animals or animal facilities are involved, the Attending Veterinarian will also be consulted to ensure the protection of both the workers and the animals.

Employees and students may be enrolled in the Occupational Health and Safety Program for a number of reasons related to the duties they are required to perform (e.g., respirator use, bloodborne pathogens exposure, scientific diving, working with certain hazardous chemicals such as pesticides, asbestos, animal care and use, etc.). All UMaine personnel listed on an IACUC protocol must be enrolled in the Occupational Health and Safety Program.

An initial evaluation for enrollment involves the completion of Pre-Employment Health & Safety Checklist prior to filling a position or whenever duties change that introduces significant new hazards. If warranted, a risk assessment will also be required from the area supervisor or hiring department. After the initial assessment has been conducted, medical consultation and/or exposure monitoring may be required. A new evaluation form must be submitted if a researcher's job responsibilities change, there is a change in health status, or it has been 3 years since the last submitted health evaluation form.

HR, working in conjunction with the department supervisor and SM, has developed procedures to ensure that existing employees and students receive the appropriate medical and exposure monitoring in a timely manner.

Whenever an assessment of duties indicates that an employee may have been exposed to a hazard for which medical monitoring is needed, the employee's supervisor will work with HR to ensure that appropriate medical consultation is available. Examinations will always be performed under the direct supervision of a licensed physician and will be at no cost to the employee. Baseline and ongoing exposure information will be provided to the physician by UMaine when required. Medical/Health History Questionnaires will be provided to the physician by the employee. Results of medical consultations and examinations are considered confidential and will not be disclosed except with employee consent or as required by law. HR will maintain copies of any required medical

information. The supervisor will only receive a report indicating the employee's status for returning to work.

Prevention is the cornerstone of this program. Initial worksite assessments, appropriate engineering controls, personal protective equipment, safe work practices, training and medical monitoring will help prevent injuries and illnesses. However, all injuries and illnesses must be immediately reported to the employee's supervisor. The supervisor is required to complete and fax the [Supervisors Workplace Injury Report](#) to SM/Risk Management within 24 hours. Investigation of these reports may indicate additional medical monitoring and worksite assessments that require assistance from HR, Occupational Health Provider, SM, Department, IACUC, etc.

Hazard Identification and Risk Assessment: The use of biohazardous materials, hazardous materials, and infectious agents are identified and described in the protocol submitted by the investigator and reviewed by the IACUC. Risks of these hazards and procedures to manage these risks are assessed and developed through the Biosafety Committee, the Radiation Safety Committee, and/or the Department of Safety Management. The Attending Veterinarian is consulted by these groups whenever a safety issue arises that is related to the use of animals in research or teaching.

As an example, a common hazard and associated risk that has been identified is exposure to rodent allergens and the subsequent development of allergies. Precautions include training to be made aware of the hazard and risks, procedures to minimize the production of aerosols, the proper use of appropriate Personal Protective Equipment (PPE) e.g., protective clothing and N95 masks, and appropriate personnel hygiene.

Personnel Training: The Department of Safety Management has several policies in place that apply to personnel (faculty, staff, and students) potentially exposed to hazardous agents. The Department of Safety Management maintains a comprehensive web-based manual of policies, programs, standards, and best business practices, and provides specific guidance in assuring compliance with the laws related to Safety Management in the workplace. A Hazard Communication Program was developed to address the specifically unique chemical hazards associated with the University of Maine Facility and to establish a mechanism for its management in order to help ensure the health and safety of all University

personnel (faculty, staff, and students) working with or around chemical substances. A Chemical Hygiene Plan applies to all university-sanctioned programs engaged in the laboratory use or creation of hazardous chemicals. Other plans, such as Exposure Control Plans, Emergency Action Plans, and an Incident Reporting and Investigation Plan are also established. University employees are required to complete Basic Safety Training on an annual basis covering a variety of common basic safety topics. Employees (faculty, staff, and students) working in laboratory or animal housing facilities are further required to complete specific area training to familiarize them with the potential hazards and safety resources relevant to specific work sites, this includes zoonoses. Health and Safety Checklists and Risk Assessments are the responsibility of individual departments. Departments are required to update the information provided whenever there is a significant change in the tasks performed or increase in risk (e.g., health status change). Faculty, staff, and students should submit a new health questionnaire if their health status has changed.

Facilities, Procedures and Monitoring: University Policies described above require departments to have mechanisms or processes in place for reporting exposure (including accidents, spills, etc.) as part of its Chemical Hygiene Plan.

Personal Protective Equipment: Adequate PPE is provided by the University. Examples include masks, head caps, gloves, lab coats, coveralls, and boots.

Medical Evaluation and Preventive Medicine for Personnel: The University requires that personnel hired to care for laboratory animals be immunized against tetanus as a condition of employment. Faculty and professional staff certify that they and their project personnel have received a tetanus immunization within the past ten years when they submit a protocol to the IACUC for approval. Students who are working with animals under an approved protocol are considered “project personnel.” They are also required to have received a tetanus immunization within the past ten years. All personnel are instructed to seek medical treatment in the event of a work-related illness or injury. For students, treatment is provided by the Cutler Health Center with appropriate follow-up care or referrals as necessary. For staff, treatment is available at any of the established medical facilities in the area.

E. *Training Programs for Personnel Who Work with Animals*

The *Guide*, PHS Policy, and the Animal Welfare Act requires that the institution ensures that all personnel caring for or using animals in research are trained to do so. All personnel named in a protocol, who work directly with animals, shall be required to complete the Collaborative Institutional Training Initiative (CITI) animal care course. The course is valid for four years. Records shall be kept of the names of individuals who complete the training and are certified to work with animals.

Beyond the web-based training program, supervisors shall be responsible for additional required training of individuals under their direction who work with animals and encouraged to call upon the veterinarian and the IACUC for assistance as needed.

F. *Whistle Blowing Policy*

The Institutional Animal Care and Use Committee (IACUC) shall provide every animal facility manager or principal investigator with a notice describing how to report concerns regarding animal care. This information shall be posted in a visible location at every animal facility. This information will also be maintained on the IACUC website.

Complaints may be made anonymously. Complaints shall be dealt with confidentially to the extent reasonably possible. No member of the University (student or employee) is subject to any reprisal for reporting any suspected violations. Protection against reprisal for employees is also guaranteed through the collective bargaining agreements and/or the State of Maine's Whistleblowers Protection Act.

G. *Protocol with External Funding*

For protocols with Federal funding, the information in the protocol must reflect the animal work described in the grant proposal. The IACUC review includes comparing the protocols with the grant to ensure that they are congruent.

H. *IACUC Policies, Guidelines and SOPs*

The IACUC has developed guidelines, Standard Operating Procedures (SOPs), and policies. It is the responsibility of the investigator to make sure that lab personnel are aware of these documents. The documents can be found on the IACUC website.

I. *Post-Approval Monitoring*

Post-approval monitoring is provided by several mechanisms listed below.

Twice a year, the IACUC inspects all animal facilities and labs where animals are being used. These inspections ensure that the institution complies with the animal care laws, regulations, policies, and guidelines. The IACUC also conducts a program review twice a year by completing the OLAW checklist. A report is provided to the Institutional Official of the findings from the inspections and the program review. The report includes minor and significant findings as well as a correction timeline for those findings.

The animal care staff monitors animals at least once per day. The Attending Veterinarian will also monitor animals as needed. Researchers and the lab members are also required to monitor their animals and to report any concerns to the animal care and/or veterinary staff. Safety Management may also inspect animal facilities and lab spaces periodically. Any animal care concerns that are noted during these inspections will be investigated by the IACUC.