UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach
Institutional Animal Care and Use Committee (IACUC)

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Procedure Title:	Program of Humane Care and Use

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1.0 Preamble

The University of Southern Maine (USM) 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 Southern 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 and 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.

USM is guided by the ethical principles of research set forth in the National Institutes of Health Guide for the Care and Use of Laboratory Animals (the Guide), NASA Principles for the Ethical Care and Use of Animals (1979), the Animal Welfare Act (7 U.S.C. 2131 et.
Seq.), U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training, the Animal and Plant Health Inspection Service (APHIS).

2.0 Definitions

2.1. **Animal** means, for the purposes of this policy, any live, vertebrate, non-human animal used or intended for use in research, and teaching, testing or related purposes.

2.2. **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.

2.3. **Assurance** means the Animal Welfare Assurance submitted by USM to the US Department of Health and Human Services, National Institutes of Health, Office of Laboratory Animal Welfare.

2.4. **The Guide** means the Public Health Service *Guide for the Care and Use of Laboratory Animals,* Eighth Edition or succeeding revised editions.

2.5. **Institutional Official (IO)** means the USM representative of senior administration who bears the ultimate responsibility for the Program and is responsible for resource planning and ensuring alignment of Program goals with the institution's mission (Guide, P. 13). The IO makes commitments on behalf of the institution to ensure compliance with the Public Health Service (PHS) Policy.

2.6. **Research Integrity Officer (RIO)** means the official who has responsibilities related to the handling of allegations of scientific misconduct involving biomedical or behavioral research or research training supported by the Public Health Service. (Department of Health and Human Services (DHHS) Office of Research Integrity).

2.7. **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.

2.8. **Significant Deficiency** means a deficiency that is or may be a threat to animal health or safety.

3.0 Policies

3.1. USM's Office of Research Integrity and Outreach (ORIO) acknowledges and accepts responsibility for the ethical care and use of live vertebrate animals within its Institutional Animal Care and Use and Biosafety Programs.

3.2. USM 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.

3.3. 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.

3.4. Researchers and instructors shall abide by *the Guide* that animals not be subjected to unnecessary pain or distress.

3.5. The IACUC shall generally consider animal welfare of greater importance than issues of experimental expense or inconvenience.

3.6. If pain or distress are necessary concomitants of an approved experiment, they shall be minimized both in intensity and in duration.

3.7. 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.

3.8. 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.

3.9. Multiple major surgical procedures on a single animal are discouraged, except when they are interrelated and essential to the primary surgical objectives.

3.10. 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.

3.11. 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. In the case of a conscious animal, the method must include rapid inducement of unconsciousness as an initial action.

3.12. Experiments involving the use of tumors, 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.

3.13. Each investigator shall consider alternatives to the use of live animals in research before presenting a protocol for the use of live animals.

3.14. 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.

3.15. 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.

3.16. 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.

3.17. 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.

3.18. If the instructional procedures will cause pain or distress, the same guidelines governing research with live animals shall also apply to their use in teaching and demonstration.

3.19. USM'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:*

3.19.1. Are sponsored by USM or one of its collaborators; *or*

3.19.2. Are conducted by or under the direction of any faculty, staff member, or student of USM in connection with his or her institutional responsibilities; *or*

3.19.3. Are conducted by or under the direction of any faculty, staff member, or student of USM using any property or facility of the University.

3.20. USM shall encourage and promote constructive communication among the Institutional Official (IO), research administrators, department chairs, deans and directors, investigators, instructors, staff, students and collaborators as a means of maintaining a high level of awareness regarding the humane care and use of live vertebrate animals.

3.21. USM shall comply with all federal, state, and local regulations pertaining to the humane care and use of animals.

4.0 Responsibilities

4.1. Responsibilities of ORIO staff, IACUC and Investigators:
It is the responsibility of the ORIO staff, Institutional Animal Care and Use Committee, and investigators to execute this Standard Operating Procedure (SOP).

4.2. 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:

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

4.2.2. The investigator or instructor shall not initiate any activity using animals without the prior approval of the IACUC.

4.2.3. The investigator or instructor shall make no significant alterations to the approved protocol without the prior approval of such alterations by the IACUC.

4.2.4. The investigator or instructor shall report at once to the IACUC any unanticipated harm to animals.

4.2.5. 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.

4.2.6. The investigator or instructor shall cooperate fully with the IACUC in monitoring the care and use of animals.

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

4.3.1. The IACUC shall review at least once every six months USM's program for humane care and use of animals, using the *Guide* as a basis for evaluation.

4.3.2. The IACUC shall inspect at least once every six months USM's animal facilities (including satellite facilities), using the *Guide* as a basis for evaluation

4.3.3. The IACUC shall prepare reports of the evaluations required above and submit the reports to the Institutional Official for Animal Welfare. The following must be included within the report to the Institutional Official:

4.3.3.1. Description of the nature and extent of the institution's adherence to the Guide and the PHS Policy, including any departures and reason for each departure.
4.3.3.2. Identification of any deficiencies in the program or facility, including classification as either *significant* or *minor* and a reasonable and specific plan and schedule for correction.
4.3.3.3. Minority views of the IACUC.
4.3.3.4. Identification of facilities accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).
4.3.3.5. Signature of a majority of the IACUC members, if applicable.
4.3.3.6. Description of the program evaluation and facility inspection process, and results of the IACUC's findings, positive and negative.
4.3.3.7. The IACUC may determine the best means of conducting an evaluation of the institution's programs and facilities and is responsible for the evaluation and report.
4.3.3.8. Final reports of the semiannual evaluations and inspections are considered full committee actions and should be reviewed and endorsed by a majority of the IACUC.

4.3.4. The IACUC shall review concerns about the care and use of animals at USM or one of its collaborators brought to its attention by any member of the community.

4.3.5. The IACUC shall make recommendations to the Institutional Official for Animal Welfare regarding any aspect of the USM's animal program, facilities, or personnel training.

4.3.6. 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.

4.3.7. The IACUC shall devise and conduct programs of education in matters relevant to the care and use of animals for the benefit of students, employees and collaborators of USM.

4.3.8. The IACUC shall maintain records of its activities.

5.0 Procedures

5.1. Institutional Animal Care and Use Committee

5.1.1. **Authority.** The IACUC is authorized to:

5.1.1.1. Approve, disapprove, or require modifications (to secure approval) in the protocols submitted to it;

5.1.1.2. Table proposed animal activities for substantive changes and expand monitoring to include:

5.1.1.2.1. Monitor animal activities for compliance with IACUC recommendations and USM Policy and Procedures for Animal Care by any means as it deems appropriate, including direct observation of the processes and procedures of animal activities, or appointment of a third party to undertake such observation;

5.1.1.3. Suspend or terminate approved use of animals, whenever a significant deficiency is found or whenever such use is not being carried out in accordance with the IACUC's requirements or when there is unexpected harm to the animals; and to

5.1.1.4. Inspect animal facilities (including satellite facilities) at any time and without prior notice.

5.1.2. **Membership.** The IACUC shall nominate and the USM Institutional Official shall appoint members of the IACUC to three-year terms. Members may be reappointed to further terms. The Institutional Official may also appoint alternates when desirable. Such alternates shall have the same voting privileges as the member for whom they substitute.

5.1.2.1. The Institutional Official shall appoint one member of the IACUC to serve as Chair for a term of three years. At the beginning of the Chair's third year of service, the Institutional Official shall appoint a Chair-Elect to succeed the current Chair. The Chair shall normally be a member of USM'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.

5.1.2.2. The IACUC shall have no fewer than five members, qualified through their combined experience and expertise to oversee USM'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.

5.1.2.2.1. The IACUC shall include at least:

- 5.1.2.2.1.1. 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 USM.
- 5.1.2.2.1.2. One practicing scientist experienced in research involving animals.
- 5.1.2.2.1.3. One member whose primary concerns are in a nonscientific area, such as an ethicist, a lawyer, or a member of the clergy.
- 5.1.2.2.1.4. One individual who is not affiliated with USM 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 USM.
- 5.1.2.2.1.5. The Biosafety Officer (BSO) for the University and a member of Safety Management (SM) shall be appointed to the IACUC as non-voting, ex officio member(s) of the IACUC.
- 5.1.2.2.1.6. 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 five members.
- 5.1.2.2.1.7. 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.
- 5.1.2.2.1.8. The IACUC may, at its discretion, invite individuals 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.

5.1.3. **Functions and Operations.**

5.1.3.1. Except when a designated member review (DMR) is used, the IACUC shall review proposed protocols only during 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.

5.1.3.2. 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.

5.1.3.3. 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* 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.

5.1.3.4. 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), veterinary care, the qualifications of personnel responsible for animal care and use. Its findings and recommendations shall be reported to the Institutional Official for Animal Welfare

5.1.3.5. Annually, the IACUC shall review USM's policies and procedures, 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.

5.2. Review of protocols

5.2.1. 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 meets the following requirements:

5.2.1.1. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research or instructional design.

5.2.1.2. 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

5.2.1.3. 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.

5.2.1.4. 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.

5.2.1.5. Medical care for animals will be available and provided as necessary by a qualified veterinarian.

5.2.1.6. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.

5.2.1.7. Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association Panel on Euthanasia, and other standard references, unless a deviation is justified for scientific reasons in writing by the investigator or instructor.

5.2.1.8. Protocols for approval of the use of animals shall be prepared by the principal investigator or instructor and submitted to the IACUC using the specific protocol review form for the study found on the USM IACUC website. Copies of project protocols shall be provided to each member prior to the review meeting.

5.2.1.9. The IACUC oversees the specific use of animals by formally reviewing animal use protocols and granting approval prior to the work commencing. The 2 valid methods of protocol review are either Full Committee Review (FCR) or Designated Member Review (DMR). (PHS Policy IV.C.2.).

5.2.1.9.1. Full Committee Review (FCR) may only be conducted at a convened meeting with a quorum (simple majority) of members present. A majority vote of the quorum present is needed to approve, require modifications in (to secure approval), or withhold approval of a protocol.

5.2.1.9.2. Designated Member Review (DMR) Prior to the review, each IACUC member is provided with a list of the proposed research projects to be reviewed and given the opportunity to call for Full Committee Review (FCR). Any member may obtain a written description of the research projects or the full protocol. If no member calls for FCR, then at least one member of the IACUC, designated by the chairperson, qualified to conduct the review, shall review those research projects and have the authority to approve, require modifications in (to secure approval), or request full committee review of those research projects. DMR may be

conducted only if all members of the committee have had the opportunity to request FCR and none have done so.

5.2.1.9.3. If a protocol is assigned more than one designated reviewer, the reviewers must be unanimous in any decision. They must all review identical versions of the protocol, and if any of the reviewers requests modifications, the other reviewers must be aware of and agree to the modifications. Failure of a unanimous decision would require the reviewers to submit the protocol for FCR. The specific method of review for a given protocol is documented in the meeting minutes, along with the outcome of the review.

5.2.1.10. 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.

5.2.1.11. Protocols receiving IACUC approval may be subject to further administrative review by the Institutional Official for Animal Welfare or by another officer of USM appointed to that purpose by the Institutional Official. 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.

5.2.1.12. 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.

5.2.1.13. 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.

5.2.2. A minor protocol change that has no substantive effect on (1) the risks to the animals or (2) the value of the data collected (meaning the change does not affect the scientific analysis of the results) may be handled administratively by ORIO, without following the procedures in 5.2.1.

5.2.2.1. Minor protocol changes include the following:

5.2.2.1.1. Correction of typographical errors;

5.2.2.1.2. Correction of grammar;

5.2.2.1.3. Contact information updates; and

5.2.2.1.4. Change in personnel, other than the PI.

5.2.2.1.4.1. ORIO will conduct administrative review to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in the occupational health and safety program, and meet other criteria as required by the IACUC.

5.2.2.2. Investigators must inform ORIO of any minor revisions to protocols by submitting an amendment to their protocol.

5.3. Significant and minor deficiencies

5.3.1. The IACUC shall identify any deficiencies in the program or facility. Including classification as either *significant* or *minor*. When any deficiency exists, it is included in the report to the Institutional Official who is responsible for the Program and is responsible for resource planning and ensuring alignment of Program goals with the institution's mission (Guide, p.13). The report will include a remediation plan with specific required actions to rectify the situation and a detailed schedule for completion of the required correction.

5.3.2. The IACUC monitors the remediation plan to ensure the required actions are rectified in the requisite amount of time. When applicable, any failure to adhere to the plan and schedule that result in a significant deficiency remaining uncorrected will be reported to the USDA in writing within 15 business days by the IACUC, through the Institutional Official, to the Animal and Plant Health Inspection Service (APHIS) and any Federal agency funding that activity.

5.4. Suspension and termination of animal use.

5.4.1. The IACUC may suspend an activity that it previously approved or if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the *Guide*, USM's Assurance, or the *Public Health Service Policy on Humane Care and Use of Laboratory Animals.* 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.

5.4.2. 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 when applicable 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.

5.5. Recordkeeping requirements.

5.5.1. The IACUC shall maintain:

5.5.1.1. Minutes of its meetings, including records of attendance, activities of the committee, and committee deliberations;
5.5.1.2. Records of protocols, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld;
5.5.1.3. Records of semiannual IACUC reports and recommendations, including minority views, as forwarded to the Institutional Official for Animal Welfare; and
5.5.1.4. Records of the qualifications of those certified to care for and use animals in USM activities.

5.5.2. 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 USM activities involving animals, and by any other person so authorized by the Institutional Official.

5.6. Reporting requirements.

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

5.6.2. The IACUC shall report to the Institutional Official at once any action to suspend or terminate approved activities, and any serious or continuing non-compliance by research personnel with the IACUC's requirements and determinations. When required, the IACUC shall provide through the Institutional Official 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.

5.6.3. The IACUC shall report to the Institutional Official any deficiencies, a remediation plan which includes specific required actions to rectify the situation and a detailed timeline for completion of the required corrections.

5.6.4. When required through an active federal assurance with the USDA significant deficiencies not corrected within the time frame of the initial corrective plan and schedule shall be reported within 15 business days to the Animal and Plant Health Inspection Service and to any Federal agency funding that activity.

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

5.6.5.1. Any change in the University's program or facilities which would place the University in a different category than specified in its Assurance;
5.6.5.2. Any change in the description of the University's program for animal care and use;
5.6.5.3. Any changes in the IACUC membership; and
5.6.5.4. Notice of the dates that the IACUC conducted its semiannual evaluations of the University's program and facilities.

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

5.7. Occupational Health and Safety Program

5.7.1. 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. USM's occupational health and safety program (for all personnel working in laboratory animal facilities or have frequent contact with animals) is as follows:

5.7.2. The Office of Research Integrity and Outreach (ORIO) is responsible for the overall management and monitoring of the Occupational Health and Safety Program.

5.7.3. In most cases, a trained health professional (THP) will be involved in conducting and evaluating the risk assessment. 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.

5.7.4. An initial evaluation for enrollment involves the completion of the Occupational Health & Safety Checklist prior to conducting animal or biosafety research. 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.

5.7.5. Whenever an assessment of duties indicates that an employee conducting animal or biosafety research may have been exposed to a hazard for which medical monitoring is needed, the employee's supervisor will work with Risk Management to ensure that appropriate medical consultation is available. Examinations will always be performed under the direct supervision of a licensed physician. Baseline and ongoing exposure information will be provided to the physician by USM 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. When medical monitoring is needed, Risk Management will maintain copies of any required medical information. The supervisor will only receive a report indicating the employee's status for returning to work.

5.7.6. Prevention is the corner stone 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 Incident Report to 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.

5.7.7. 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 risks are assessed and developed through the Institutional Biosafety Committee (IBC) or Safety Management (SM). 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.

5.7.8. 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 type masks, and appropriate personnel hygiene.

5.7.9. Personnel Training: SM has several policies in place that apply to personnel (faculty, staff, and students) potentially exposed to hazardous agents. SM 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

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 themselves 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 may inform supervisors of any health change (e.g., pregnancy, illness), so that the existing risk assessment can be reviewed and updated based on the person's change in health status. After reviewing the risk assessment, if personnel have additional concerns based on their change in health status, they may be advised to consult their physician.

5.7.10. 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.

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

5.7.12. Medical Evaluation and Preventive Medicine for Personnel: USM 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 research personnel are instructed to seek medical treatment in the event of a research or work-related illness or injury. All research personnel may seek direction of where to obtain treatment by contacting Risk Management.

5.8. Training Programs for Personnel Who Work with Animals

5.8.1. 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(s). The course(s) are valid for four years. Records shall be kept of the names of individuals who complete the training and are certified to work with animals.

5.8.2. "Working With The IACUC" CITI Training is required by all investigators, key personnel, faculty advisors, and research staff working with animals.

5.8.3. “Wildlife Research” CITI Training is required by all investigators, key personnel, faculty advisors, and research staff working with animals during a field study or wildlife study.

5.8.4. For University of Southern Maine investigators, key personnel, faculty advisors, and research staff the “Basic Safety Training” provided by the University of Maine System is required each academic year. If the University’s Training is not available, the CITI “Introduction to Biosafety” Training may be a substitute.

5.8.5. 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.

5.9. Research Misconduct and Whistle Blower Policy and Protections.

5.9.1. Research Misconduct (as defined under federal regulation and USM’s policy for “Alleged Research Misconduct”) means:

5.9.1.1. The knowing fabrication, falsification, or manipulation by a researcher of data or information;
5.9.1.2. The knowing theft by a researcher of data, materials, or information, including but not limited to plagiarism;
5.9.1.3. Implicit in this definition of misconduct is that a preponderance of the evidence proves that fabrication, falsification, or plagiarism; theft; non-compliance with legal requirements; or disregard of associate conduct was committed intentionally, knowingly, or recklessly, and not merely carelessly.

5.9.2. At any time, a USM community member may have confidential discussions and consultations about concerns of possible research misconduct with the Research Integrity Officer (RIO) and will be counseled about appropriate procedures for reporting allegations. According to USM’s anti-retaliation policy individuals who have in good faith made an allegation of research misconduct ("whistle-blower") will not be subject to disciplinary action or retaliation.

5.9.3. If there is a determination that retaliation has occurred against a whistleblower, the Deciding Official shall determine what remedies are appropriate to satisfy the USM’s obligation to protect whistleblowers. The Deciding Official shall, in consultation with the whistleblower, take measures to protect or restore the whistleblower's position and reputation, including making any public or private statements, as appropriate. In addition, the Deciding Official may provide protection against further retaliation by monitoring or disciplining the retaliator.

5.10. Noncompliance

5.10.1. See Standard Operating Procedure IACUC - 002 Noncompliance.

5.11. Reporting Concerns

5.11.1. See Standard Operating Procedure IACUC - 003 Reporting Concerns

5.12. Contingency Planning

5.12.1. See Standard Operating Procedure IACUC - 004 Contingency Planning