



**The University of Southern Maine
Policies and Procedures for Animal Care and Use**

**Office of Research Compliance
Division of Provost's Office**

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I. ETHICAL PRINCIPLES GOVERNING THE CARE AND USE OF LABORATORY ANIMALS

The development of knowledge necessary for the improvement of the health and well-being of humans and animals requires experimentation with a wide variety of animal species. The University of Southern Maine (USM) is guided by the ethical principles of research set forth in the [National Aeronautics and Space Administration Principles for the Ethical Care and Use of Animals \(1979\)](#), the regulations of 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](#) and [The Guide for the Care and Use of Animals](#). USM's policies and procedures involving animal care and use have been formed to comply with the Federal, state and local laws and regulations relating to animals.

The use of animals in research, teaching or testing engenders responsibilities for the care of the animals, the scientific community, and society in general. The University of Southern Maine recognizes three basic principles particularly relevant to the ethics of using animals: respect for life, societal benefit, and non-maleficence.

Respect for life: USM respects all life. This principle ensures that animals used will be of an appropriate species and health status, and involve the minimum number of animals needed to obtain valid results. Selection of appropriate species should consider cognitive capacity and other morally relevant factors of species considered for use. Relevant models, computer simulation, and in vitro systems should be considered and used whenever possible.

Societal Benefit: The advancement of biological knowledge and improvements in the protection of the health and well being of both humans and other animals provide strong justification for biomedical and behavioral research. This principle of societal benefit entails that where animals are used, the assessment of the overall ethical value of such use should include consideration of the full range of potential societal goods, the populations affected, and the burdens that are expected to be borne by the subjects of the research.

Non-maleficence: The minimization of distress, pain, and suffering is a moral imperative. Unless the contrary is established, investigators should consider that a painful procedure is defined as any procedure that would reasonably be expected to cause more than slight or momentary pain and/ or distress in a human to which that procedure is applied.

The University of Southern Maine also recognizes and accepts its responsibilities for protecting these principles for animal activities. These ethical principles will apply to all use and care of animals:

1. Sponsored by the University of Southern Maine; or
2. Conducted by or under the directions of any employee or agent of the University of Southern Maine in connection with their responsibilities; or
3. Conducted by or under the direction of any employee or agent of the University of Southern Maine using any property or facility of this University.

The University of Southern Maine will exercise administrative oversight of all animal activities consistent with Federal Policy and any additional policies promulgated by the Board of Trustees of the University of Maine System. All Federally supported animal care and use will comply with any animal care and use regulations and policies of any relevant regulatory department or Agency. In reviewing animal activities, the Institutional Animal

Care and Use Committee will satisfy all of the responsibilities required any animal care and use regulations and policies of any relevant regulatory department or Agency.

II. Definitions

Animal - Any live vertebrate animal intended for use in research, research training, education, experimentation, biological or related purposes or any non-live dog or cat.

Animal Care and Use Violations - Any unauthorized animal use or care is considered an animal care and use violation.

Animal Facility-Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities used for animal confinement, transport, maintenance, breeding, experimental procedures or surgery.

Institutional Official - The USM official who is legally responsible for executing the Animal Assurance with the Public Health Service.

Significant Deficiency - A significant deficiency is a deficiency in animal care and use that is inconsistent with this Policy in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals or humans exposed to the animals.

Satellite Facility- Any containment rooms, areas, or enclosures outside a core facility or centrally designated or managed area where animals are housed more than 24 hours.

III. USM Policies

A. Policies, Regulations, and Standards for Care and Use of Laboratory Animals

It is the purpose of this Policy is to set forth and maintain proper measures to ensure the ethical care and use of all animals involved in research, research training, education and biological testing activities (hereinafter referred to as activities) conducted or supported by USM.

All proposed USM activities shall ensure that:

I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et. seq.) and other applicable Federal laws, guidelines, and policies.

II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.

III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.

IV. Proper use of animals includes the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices and is imperative for activities at USM. Unless justified for scientific validity investigators must consider

that procedures that cause pain or distress in human beings will cause pain or distress in other animals.

V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures will not be performed on anaesthetized animals paralyzed by chemical agents.

VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved must be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.

VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. The housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other appropriately trained individual experienced in the proper care, handling, and use of the species being maintained or studied. Veterinary care shall be available as needed.

VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals and training on the USM Policies and Procedures for the Care and Use of Animals.

IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions will not be made solely for the purposes of teaching or demonstration.

B. Animal Care and Use Misconduct (Whistle Blower policy and protections)

Animal care and use misconduct is defined as a willful disregard of USM's Policy and Procedure for Animal Care and Use. Anyone found to have engaged in willful misconduct, is subject to disciplinary action by the IACUC Committee and the University's Research Conduct Officer. Faculty, staff, and students may confidentially disclose what they believe to be misconduct to the Office of Research Compliance to begin investigation as defined in USM Policy on Alleged Misconduct in Research and Other Professional Activities accessible on line at <http://www.usm.maine.edu/~osp/conduct.htm>. Individuals who have in good faith made an allegation of misconduct ("whistle-blower") will not be subject to disciplinary action nor retaliation. Retaliation against a "whistle-blower" will be construed as an act of misconduct.

C. Occupational Health Program

Exposure to animal includes a risk of developing some adverse health outcomes. The risks of animal associated illness include transmission of infection, respiratory illness, allergies and even asthma. However, proper animal handling procedures and personal protective equipment can minimize these risks. All animal handlers are encouraged to participate in the USM Occupational Health Program for Animal Handlers. The program provides educational information on the health risks associated with animal handling and ways to minimize the chance of developing illness as a result of prolonged animal

contact. The program also offers ongoing monitoring of animal related health status. The Director of Safety and Health may be contacted for comprehensive information about the Occupational Health Program.

D. Animal Welfare Information Center and AGRICOLA

The Animal Welfare Information Center is part of the National Agricultural Library (NAL), which is located in Beltsville, MD. The Center was established in December 1986 as mandated by amendments to the Animal Welfare Act. It is the focal point for those interested in obtaining information or publications covering many aspects of animal welfare.

AGRICOLA (Agricultural On Line Access) is a bibliographic database consisting of records for literature citations of journal articles, monographs, theses, patents, software, audiovisual materials, and technical reports relating to all aspects of agriculture. Of the more than 2 million entries, one-fifth of the database is devoted to laboratory animal science, veterinary medicine, and animal production. It is accessible through the Anschutz Science Library.

The Animal Care Unit has obtained the following aids: "AGRICOLA," "Getting started on AGRICOLA," and Searching AGRICOLA for Animal Welfare." AGRICOLA workshops are also held periodically. Brochures and training schedules are available upon request from AWIC.

E. The Reduction, Refinement and Replacement of Animal Activities

1. Reduction - The numbers of animals used in research can be reduced by a thorough literature review of the proposed activities, basing animal numbers the statistical significance required for sufficient data points, using disease free animal and sharing animal tissue whenever possible

Literature review

No experiment using animals should be performed without a thorough review of the literature to eliminate the possibility of needless repetition and to determine the most appropriate model to answer a particular research question. Through the inter-library loan system, the campus libraries have access to literature concerning all aspects of animal experimentation. Specific information may be sought using a variety of databases including AGRICOLA, which is maintained by the National Agricultural Library. AGRICOLA is accessible online. Consult the library staff for assistance with searches.

Use based on requirements to achieve statistical significance

All experiments should be planned to provide sufficient data points to determine statistical significance. Using insufficient numbers of animals may require a repetition of the experiment and, therefore, may be as undesirable as using too many animals. Formulae for estimating the number of animals needed for a particular experiment may be found in Statistical Methods for Rates and Proportions 2nd ed. by Joseph L. Fleiss and Biostatistical Analysis 2nd ed. by Jerrold H. Zar or may be obtained through consultation with a biostatistician.

Disease free animals

While the cost of disease free animals, sometimes called SPF (Specific Pathogen Free), is much greater initially, the long term benefits of using such animals usually far outweigh the initial cost. Even sub clinical infections can alter an organism's responses to research-induced challenges, thereby invalidating results.

Sharing animals or tissues

In some cases, the organs, tissues, antibodies, etc. may be commercially available. Several investigators sharing the organs of a single animal reduces the number of animals necessary and the cost to the investigator.

2. Refinement refers to refining techniques or protocols to reduce stress to the animal subject.

Whenever possible, investigators should design experiments so that death is not the end point. Minor modifications of the approach to the experimental problem may allow euthanasia of an animal before it suffers significant discomfort or anxiety. Along the same lines, when passaging tumors or growing tumors in vivo, efforts should be made to collect tissues or evaluate effects prior to the time that the animal is incapacitated.

Anesthetic, analgesic, or tranquilizing agents should be administered for any procedure potentially causing more than minimal or momentary pain or distress to the animal. Exceptions must be justified and will receive particular attention in both consideration prior to approval and monitoring during the procedure by the IACUC.

The principal investigator should be alert to, and recognize signs of, pain or distress in the species with which he is working. Changes in dietary or grooming habits or changes in posture or temperament may indicate that an animal is in pain or distress. If investigators have any questions, they should consult the ACU health care staff.

3. Replacement refers to the implementation of alternative methods other than animal use to fulfill the specific aims of a teaching, testing or research project.

Teaching new techniques

New techniques should be demonstrated or practiced on models or cadavers. Videotapes and slide-tape presentations should be developed and used as much as possible in training programs.

Alternative or adjunctive methods

While an intact biological system may be required to answer some research questions, tissue culture, or other in vitro techniques, including computer or mathematical modeling may provide satisfactory alternative or adjunctive methods.

Using the lowest species on the phylogenic scale possible to obtain desired data.

IV. Institutional Animal Care and Use Committee (IACUC)

A. Membership

The Chief Administrative Officer (the President) of USM shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. Voting members are appointed to the IACUC for 3-year terms. Each member must attend 50% or more of scheduled meetings per year in order to maintain membership status.

The committee shall consist of not less than five members, and shall include at least:

- (1) One Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program authority and responsibility for activities involving animals at the institution (see IV.A.1.c.);
- (2) One practicing scientist experienced in research involving animals;
- (3) One member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy); and
- (4) One individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution.

An individual who meets the requirements of more than one of the categories detailed above. (1)-(4) may fulfill more than one requirement. However, no committee may consist of less than five members. More than 3 members may not represent one department.

The IACUC meets at least twice yearly or more frequently as needed. No member of the IACUC may vote on or be present for the IACUC review and discussion of a proposal in which the member has a financial or institutional conflicting interest. In such instances the IACUC member will excuse herself/himself from the IACUC meeting until the IACUC takes action on the protocol.

B. Responsibilities of the IACUC

The charge of the University of Southern Maine Institutional Animal Care and Use Committee (IACUC) is to assure the humane care of animals used in biomedical and behavioral research, teaching, and testing. The USM IACUC is a standing committee that oversees animal use and care at USM. All animal users at USM must abide the regulatory requirements pertaining to the acquisition and use of live vertebrate animals for research, teaching, or other animal activities as outlined the USDA Animal Welfare Act, NIH requirements, and [The Guide for the Care and Use of Animals](#), USM Standard Operating Procedures for Animal Care and Use, and the contents of this Policy.

All animal use and research must be reviewed and approved by the IACUC prior to ordering, breeding or using animals in research, teaching or testing at USM. The IACUC is responsible for assuring appropriate use, care, and treatment of all vertebrate animals used for University activities, and has the authority to approve or withhold approval of protocols for all such activities involving animals in accordance

with the Public Health Service Policy on the Humane Care and Use of Laboratory Animals and regulations of the Animal Welfare Act (Public Law 99-158)

The responsibilities of the IACUC shall with respect to all animal activities include:

- (1) Review at least once every six months the institution's program for humane care and use of animals, using the [Guide](#) as a basis for evaluation;
- (2) Inspect at least once every six months all of the institution's animal facilities (including satellite facilities) using the [Guide](#) as a basis for evaluation;
- (3) Prepare reports of the IACUC evaluations conducted as required by, and submit the reports to the Institutional Official
- (4) Review concerns involving the care and use of animals at the institution;
- (5) Make recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training;
- (6) Review and approve, require modifications in (to secure approval) or withhold approval of those components of animal activities related to the care and use of animals as specified in IV.C. of this Policy;
- (7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities;
- (8) Suspend an activity involving animals in accordance with the specifications set forth in IV.C.6 of this Policy;
- (9) Attend 50% of scheduled IACUC meetings.

C. Authorized IACUC Powers

The Scope of IACUC powers is limited to the care and use of animals at USM and may not exceed that which is required by Federal, State or local regulations. Accordingly the IACUC is empowered with the following actions:

1. Approve proposed animal activities as submitted to the committee;
2. Approve proposed animal activities contingent upon specific revisions;
3. Table proposed animal activities for substantive changes;
4. Disapprove proposed animal activities;
5. 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, and/or appointment of a third party to undertake such observation; and to
6. Suspend or terminate animal activities, whenever the animal activities are not conducted in accordance with the IACUC's requirements, or for minor or major

proposal violations, or whenever it has been associated with an unexpected harm to animal subjects if deemed appropriate by the IACUC, its designee or Institutional Official in accordance with the procedures set forth in Section III. H. 3 of this policy.

D. IACUC Member Registration with OLAW

All voting IACUC member names and qualifications are registered with the Office of Animal Laboratory Welfare. The ORC will notify OLAW within 15 working days of any changes to membership.

E. Education of IACUC Members

All new members of the IACUC will be oriented to the USM Animal Care and Use Policies and Procedures by the Director of the Office of Research Compliance. The Manager of the Animal Care Facility in cooperation with the attending Veterinarian will provide education to members on up to date and accepted animal procedures.

F. Termination of Membership

An IACUC member may be terminated for serious misconduct or breach of membership duties if approved by a gross majority of voting IACUC members. This action may only be taken at a convened IACUC meeting.

G. Rules for Program Review and Facilities Inspections

The IACUC will review the animal care and use program on a semi-annual basis (every six months) to verify and ensure a quality animal care and use program. The Program Review will include an assessment of the overall functioning of the IACUC, the adequacy of USM Policies and Procedures for Animal Care and Use, Occupational Health Program, and Veterinary procedures as outlined by OLAW. The IACUC will use the sample forms provided by OLAW to perform the Program Review.

The IACUC will inspect all USM animal facilities, including satellite facilities, as part of the semi-annual program review using forms and procedures outlines by OLAW. In addition, any member may, at their discretion, inspect any USM animal facility at any time un-announced to verify that IACUC authorized procedures are being followed. The semi-annual inspection will include;

- a. Animal Rooms, enclosures and housekeeping
- b. Cage wash and sanitation procedures
- c. Procedure rooms and areas
- d. Transportation vehicles
- e. Environmental Conditions
- f. Documentation of problems

The IACUC will report the findings of the Semi-annual program review and facilities inspection directly to the President and the Institutional Official. This report will be maintained by administration and made available to OLAW upon request. The reports must contain a description of the nature and extent of the institution's adherence to the [Guide](#) and this Policy and must identify specifically any departures from the provisions of the [Guide](#) and this Policy, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies.

A significant deficiency is one which, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals or animal handlers. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency. If some or all of the institution's facilities are accredited by AAALAC or another accrediting body recognized by PHS, the report should identify those facilities.

The IACUC will make recommendations for increasing the quality of the animal care program to the Institutional Official. This may include changes to IACUC policies and procedures, however, the policy must meet the basic requirements of The Guide, and University of Maine System Policies and Procedures. The Administration may impose additional policy requirements as needed to protect the institution. These requirements cannot be overturned by the IACUC.

The IACUC will report annually to the Institutional Official and President regarding the state of animal care and use at USM. This report will follow OLAW guidelines.

H. Rules for Review of Animal Proposal

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

1. Criteria for Animal Proposal Approval

The IACUC shall determine that the research project conforms to the institution's Assurance and meets the following Criteria:

- (a) Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research 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.
- (c) Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed 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 contribute to their health and comfort. The housing, feeding, and non-medical 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 (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

2. Procedure for Animal Proposal Review

Expedited Review

Prior to the review, each IACUC member shall be provided with a list of proposed research projects to be reviewed. Written descriptions of research projects that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, full committee review of those research projects. If full committee review is not requested, at least one member of the IACUC, designated by the chairperson and 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.

Full Board Review

If full committee review is requested, approval of those research projects may be granted only after review at a convened meeting of a majority of the IACUC and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of a research project 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 the review of 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.

Investigator Notification

The IACUC shall notify investigators and the institution in writing of its decision to approve or withhold approval of those 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 an opportunity to respond in person or in writing.

Continuing Review

The IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC or at least yearly, including a complete review in accordance with Section IV.C.1.4. of the this Policy, at least once every three years.

3. Procedure for Protocol Suspension

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 USM Policy and Procedures Animal Care and Use. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.

If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW.

Applications and proposals that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the institution. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

I. Procedures for Handling Concerns and/or Discrepancies

Any person who has a concern over any aspect of animal care or use (including but not limited to animal neglect, improper handling, or a discrepancy between approved IACUC procedures and actual procedures) may confidentially and anonymously report their concerns. Concerns may be made to the Director of Research Compliance, the Animal Care Manager, the Institutional Veterinarian, or the University Ombudsperson. All reports will be assessed by the Director of Research Compliance and the Chair of the IACUC. If the assessment reveals an animal protocol violation, the procedures at IV. J of this Policy will be followed and if these activities are considered misconduct all applicable procedures for Alleged Misconduct will also be followed. All reported complaints will be communicated to the IACUC at the next convened IACUC meeting, and included in the IACUC Annual Report.

J. Procedures for Animal Care or Use Violations

An animal activity violation occurs when there is a variance between the activity that has been reviewed and approved by the IACUC and the actual activities being performed. A violation may be minor or major in nature. All incidents of alleged or known protocol violations may be investigated using the following procedures;

1. Minor animal activity violation:

Animal activity violations 1) have no substantive effects on animal welfare or to animal handlers or 2) the value of the data collected (meaning the violation does not confound the scientific analysis of the results); and 3) did not result from willful or knowing misconduct on the part of the investigator(s). The following steps will be taken to investigate minor protocol violations:

a. A fact finding inquiry process may be initiated by the IACUC chair in cooperation with the Director of Research Compliance (DRC)

b. The IACUC chair and the DRC will analyze all information gathered regarding the protocol violation and compare it to the approved protocol. When necessary, the chair and the DRC will consult with experts in the particular area of research in order to make definitive, unbiased and educated decisions regarding the

violation. A conclusion will then be made regarding the seriousness of the violation.

c. If the findings support all three criteria noted above for a minor protocol violation, the IACUC chair will notify the principle investigator in writing that indicates what must be done (if anything) to correct the conditions that lead to the violation and what (if anything) must be communicated to the research participants.

d. The IACUC chair will present a summary of the violation, process, facts, and conclusions at the next scheduled convened IACUC meeting.

e. If the findings support that the violation 1) has a substantive effect on the risks of the research subject, 2) has a substantive effect on the value of the data collected, and 3) resulted from a willful or knowing misconduct on the part of the investigator, the matter will be treated as a major protocol violation.

f. If the findings from steps a or b above do not support that a violation has occurred, the matter will be dropped.

2. Major Protocol Violation

Major protocol violations include violations that 1) have or pose a significant risk of substantive harm to research participants, 2) damage the scientific integrity of the data collected; or 3) there is evidence of willful or knowing misconduct on the part of the investigator; or 4) the investigator(s) demonstrate other serious or continued noncompliance with federal, state or local research policy, laws or regulations. In such cases the following steps will be taken to investigate major protocol violations:

a. A fact-finding inquiry process will be initiated by the IACUC chair in cooperation with the Director of Research Compliance (DRC)

b. The chair will convene a hearing committee to consider all the facts of the case and to meet the investigator (s). The hearing committee will consist of;

1. IACUC Chair
2. ORC Director of Research Compliance
3. Associate Provost for Graduate Studies and Research
4. Two or more representatives from the PI's department or discipline
5. Two or more community members
6. A representative of the University of Maine System Counsel's Office.

c. If the hearing committee finds any of the four criteria noted above for major protocol violations, the IACUC Chair will immediately suspend the protocol. (Note: this does not preclude the IACUC chair from suspending the protocol in advance of the hearing if, in the chair's assessment, the conditions in 45 CFR 46.113 have been met and warrant an emergency protocol suspension).

d. If suspension of the protocol or study procedures would result in harm to the enrolled research participants, the chair will request that the PI's department chair assign PI duties to another qualified person and submit a Project Revision Amendment Form explaining this substitution and indicating temporary closure of the study. In this situation the official action will be the suspension of the investigator.

e. Any protocol or investigator suspension will be reported directly to the DRC who will determine the appropriate federal agencies or sponsors to notify, and the DRC will prompt the IO to make such notification in writing.

f. Depending on the nature or the seriousness of the violation, the hearing committee may elect to direct the IACUC to audit all protocols that involve the investigator in question. The IACUC chair may delegate this duty to a designee or appropriate third party.

g. If the findings of the hearing committee support research misconduct, the provost will be notified and a USM Misconduct Investigation will ensue.

h. A summary of the issue, process, facts, conclusions and actions will be presented at the next scheduled IACUC meeting. A written summary will be forwarded to the PI, the PI's department chair, and the appropriate dean or director. A copy will be retained in the IACUC study file.

If an investigator disagrees with the findings or requirements of the Committee, investigators have the right to appeal the Hearing Committee's Decision to the Provost. The Chair will forward all information gathered by the inquiry or hearing process to the Provost who will consider it along with any additional information provided by the investigator. The Provost's decision will be final.

V. Animal Investigator/User Responsibilities

A. Responsible Animal Care and Use

The University of Southern Maine is committed to the highest ethical standards of all research, care, and use of animals. It is the primary responsibility of the investigator or handler to uphold the ethical standards of research as defined in this Policy and the ethical guidelines that govern each researcher's academic discipline(s). The individual researcher is responsible for adhering to all pertinent animal protection laws and rules, and University of Southern Maine and University of Maine System Policy regarding animal activities.

1. Ethical Decisions for Animal Use

There has been opposition to the use of animals as study subjects for biomedical research extending back to Victorian England (1). While scientists of that era acknowledged the need for animals as study subjects, they also expressed concerns about the humane use of their animal subjects (2). The major concern, then and now, is needless suffering, human or nonhuman.

There are criteria that should always guide the investigator in assessing the use of animal subjects for study.

- (1) Are animals necessary for instituting the study?
- (2) Is the selected animal species appropriate for the study?
- (3) What is the likelihood that the model will provide accurate information to answer the question under study?
- (4) Is the proposed study unique or repetitious of already well-established data?

(5) What is the cost in terms of money and numbers of animals to answer the question in relation to the potential importance of the data?

Major medical advances through the last few centuries have been very dependent on data from the study of animals including work by: Jenner, Virchow, Lister, Koch, Erlich, Pavlov, Fleming, Harvey, Bernard and Pasteur. The data from studies in a particular area are like a ladder whose exact and eventual destination cannot be appreciated fully.

There are also groups who philosophically disagree with the use of nonhumans by humans for any purpose. While some groups promote animal welfare and focus their efforts on ensuring the proper care and humane treatment of animals, others promote legal rights for animals and espouse that animal rights are similar to those available to people in this country. To preserve the privilege of using animals to address important scientific problems and alleviate both animal and human suffering through basic, biomedical, and behavioral investigation, the research community must be involved in educating the public about the value of their work while at the same time following a responsible program of the "3 Rs" (Reduce, Replace and Refine).

Each individual will have to decide for him or herself whether or not it is ethical to use animals to conduct studies which may result in a significant savings in human life or alleviation of human suffering. It is also important to recognize that aesthetics and humaneness cannot easily be correlated. Many procedures that may appear aesthetically displeasing could be humanely performed without pain or discomfort. Investigators must continually be aware of and sensitive to how others may view their procedures.

With the privilege of using animals in research goes responsibility and accountability. Careful planning and use of animals in biomedical research is essential if the proposed study is to have quality and value. From the outset, the investigator must be thoroughly knowledgeable about what is already known about the problem and have a clear vision of the potential benefits that could come from the proposed study. Equally important is the attention paid to every detail; selection of appropriate species, careful determination of the numbers of experimental and control animals needed for accurate interpretation of data, as well as housing and caring for the animals in an environment which will ensure their health and comfort and result in valid, reproducible results. It cannot be assumed that because a procedure is done on humans without anesthetic, that it can be performed on an animal without regard to possible pain. In the medical arena, a physician's decisions and actions influence the patient's morbidity and mortality, thus are not made frivolously. Likewise, the manipulation of the life of an animal research subject should be approached with like forethought and consideration.

B. Animal Activity Misconduct

Animal activity misconduct is defined as a willful disregard of USM's Policy and Procedures for Animal Care and Use. Anyone found to have engaged in willful misconduct, is subject to disciplinary action by the University via the Conduct Committee. Faculty, staff, and students may confidentially disclose what they believe to be misconduct to the Office of Research Compliance to begin investigation as defined in USM Policy on Alleged Misconduct in Research and Other Professional

Activities accessible on line at <http://www.usm.maine.edu/~osp/conduct.htm>. Individuals who have in good faith made an allegation of misconduct ("whistle-blower") will not be subject to disciplinary action nor retaliation. Retaliation against a "whistle-blower" will be construed as an act of misconduct.

C. Conflict of Interest

Inasmuch as research is concerned, the University Conflict of Interest Policy promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research will be biased by any conflicting financial interest of an Investigator.

To ensure the continued confidence of the people of Maine in the University and its personnel, individuals serving the University and University of Southern Maine shall at all times act in a manner consistent with their public responsibilities to the University and shall exercise particular care that no real or perceived detriment to the University results from conflicts between personal interests and those of the University. Conflict of Interest situations, or the appearance of conflicts of interest, either financial, personal or organizational, have the potential to result in serious harm and direct losses to the University. The losses are often difficult to detect and include not only direct monetary losses and loss of confidence in the University, but also negative publicity and erosion of employee morale.

It is the policy of the University of Maine System and University of Southern Maine that its officers, faculty, staff and others acting on its behalf have the obligation to avoid ethical, legal, financial or other conflicts of interest and to ensure that their activities and interests do not conflict with their obligation to the University or to its welfare. All researchers are expected to uphold the USM Policy on Conflict of Interest found on the Office of Sponsored Programs Web Site <http://www.usm.maine.edu/~osp/conflict.htm>.

D. Changes in Approved Animal Activities

A minor protocol change 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). Investigators must inform the ORC of minor revisions to protocols. A copy of the changes will be added to the approved protocol file.

A major protocol change 1) has or poses a significant change in risk associated with animal use, or 2) changes the scientific value of the data collected. Investigators who wish to make major revisions to their protocols must seek IACUC review and approval prior to the initiation of a major change to the protocol. To initiate this process the investigator may complete an Animal Protocol Revision Amendment Form and any altered tools or forms for IACUC review.

The IACUC will periodically audit the procedures in approved protocols either by discussion with or by direct observation of the Investigator by an IACUC member, ORC official or appointed third party to verify that only approved procedures are performed. Researchers who fail to notify the IACUC of minor changes or instigate major protocol changes without IACUC approval will be subject to the IACUC Procedures for Protocol Violations (see Section IV. H). Performing research without IACUC approval will be considered as research misconduct and will be handled according to the USM Alleged Misconduct policy. Please contact the Office of Research Compliance for additional information.

E. Report of Unforeseen and Adverse Events

All adverse events of physical or cognitive harm, threats to safety of animal users or animal subjects must be immediately communicated to the Office of Research Compliance and the IACUC Chair. All adverse events will be communicated to the IACUC at the next scheduled IACUC meeting. All unanticipated research events that include human research subjects in federally sponsored research will be reported to the Office of Animal Laboratory Welfare, as well as any federal agency or sponsor that provides funding for the animal care and use by the Institutional Official.

VI. IACUC Application Requirements

A. Instructions for Developing and Submitting Animal Use Proposals

Investigators must seek prospective approval of all animal care and use activities at USM. To apply for approval, use the IACUC proposal application available on line at (www.usm.maine.edu/orc/iacuc). The Investigator must use only approved animal procedures as outlined in the USM Standard Operating Procedures for Animal Care and Use (SOP). Specific reference to the name and number of the SOP should be made directly on the application. Prior to the submission for approval of a new procedure, the investigator must consult with the Animal Care Manager and the attending Veterinarian to insure that the procedure is consistent with good clinical practices, and assure that an alternative method does not exist that would meet USM standards for reduction, refinement and replacement of animals (see section III. E of this Policy).

B. Training Program on the Use of Animals

All persons handling animals at USM must complete required animal handling education including basic handling, and when applicable education on invasive or surgical procedures by authorized personnel. In addition, any person who receives funds from the National Science Foundation or the National Institutes of Health must attend Responsible Research Conduct training offered by the Office of Research Compliance. Faculty teaching disciplines that routinely implement animal research should include basic animal welfare requirements in the courses offered at USM. Educational sessions are available to all students, faculty and staff.

VII. Facilities and Services

A. Facilities

All animal facilities utilized by the University of Southern Maine shall be in compliance with federal and state standards. The USM animal facility will have over 3,000 square feet of space available and shall contain feed & bedding storage, administration, isolation, cage-wash, and animal housing areas. The animal facility will have restricted access as well as specific training for facility entry.

B. Housing Recommendations

Housing recommendations follow those set forth in the Guide for the Care and Use of Laboratory Animals. All animals shall be housed in species appropriate caging and individual characteristics such as size, sex, and social behavior shall be brought under consideration. All animals will be kept in rooms that have temperature, light,

and humidity strictly controlled. The size of the cage and the amount of animals per cage will be in accordance with the spacing requirements stated in the Guide.

C. Health Care Regimens for Incoming and Long Term Animals

All animals will be observed daily, including holidays and weekends, for any signs of pain, distress, or illness. Temperature and humidity will also be monitored daily to maintain stable environmental conditions. If it is observed that the animal is having difficulty, then the principal investigator shall be contacted and if necessary, the veterinarian shall be consulted. The animal will be treated according to the veterinarian's instructions. If euthanization is warranted, then it shall be done following the recommendations put forth in the AVMA Report on Euthanasia.

Any incoming animals will be given a three-day stabilization period to allow for observance of failing health or injury as well as to acclimate the animals to its new environment.

D. Controlled Drug Procedures Controlled Substances Act

Potentially addictive or habituating drugs for human or animal use are classified under this law. Examples of controlled substances include barbiturates and narcotics. The Department of Justice, Drug Enforcement Administration (DEA), enforces this law and requires appropriate security and record management of these substances.

VIII. Biological and Physiological Data on Laboratory Animals

A. Basic Biological and Physiological Values. Consult the attending USM veterinarian for up to date species-specific biological and physiological values.

B. Handling Common Laboratory Species

Handling & restraint will be kept to the minimum amount necessary to perform the task at hand. Animals should only be handled by trained personnel and by proper technique. Incorrect handling can result in injury to the handler as well as the animal. Proper handling and restraint procedures for each USM species are covered in standard operating procedures to be approved by IACUC.

C. Injections to Common Laboratory Species

Injections shall be made via one of the following methods: ID-intradermal, IM-intramuscular, SC-Subcutaneous, IP-intraperitoneal, or IV-intravenous. Injections will be given through the method that is best suited for the reduction of pain and distress in the animal and the substance to be injected. Only trained personnel shall be allowed to administer injections. All injections will occur using a sterile syringe and needle. Proper technique is covered in standard operating procedures to be approved by IACUC.

D. Blood Collection from Laboratory Animals

Methods for blood collection in rodents shall include retro-orbital bleed, withdrawal from the tail vein or cardiac puncture. Retro-orbital bleeds should only be used in conjunction with proper anesthesia. Cardiac puncture will only be performed as a terminal procedure and the animal is required to be properly anesthetized prior to the

start of the procedure. Proper techniques are again covered in IACUC approved standard operation procedures

E. Nutrition

Each species of laboratory animal under the care of the USM Animal Facility shall receive clean, fresh food that meets the nutritional needs for the individual species. Any changes in the animals diet for research purposes will have to gain prior written approval from the IACUC Committee.

F. Basic Food and Water Requirement

Most rodents will be fed ad libitum with fresh clean water available at all times. The only exceptions will be for research purposes. Any changes in this policy will require written justification and approval from the IACUC Committee.

G. Animal Diets

All animal diets will be purchased from a reputable commercial source and will be appropriate for those species involved. All animal diet materials will be stored according to the manufacturer's and the Guide's recommendations and in accordance with federal, state and local regulations.

XI. Anesthetic, Analgesic, Tranquilizing, and Euthanizing Agents for Laboratory Animals

A. Legal Requirements

Potentially addictive or habituating drugs for human or animal use are classified under the Controlled Drug Procedures Controlled Substances Act. Examples of controlled substances include barbiturates and narcotics. The Department of Justice, Drug Enforcement Administration (DEA), enforces this law and requires appropriate security and record management of these substances. All controlled substances will be purchased through the Animal Care Facility, and written approval to use controlled substances must be issued by the Office of Research Compliance.

B. Anesthetics, Analgesics, and Tranquilizers

All anesthetics, analgesics, and tranquilizers will be used in accordance with federal and state laws as well as the consulting veterinarian's instructions. Only those trained in the use of these agents will be allowed to handle and administer them. When required, specific drugs will be kept in a double lock box with strictly limited access and a register of usage kept. This is in accordance with the Controlled Substances Act.

D. Skeletal Muscle Relaxants

Any skeletal muscle relaxant that is classified under the Controlled Drug Procedures Controlled Substances Act will be stored and used in accordance with this law. Only trained personnel will be allowed to handle & administer drugs of this type under the supervision of the consulting veterinarian.

E. Euthanasia

All euthanasia shall occur under the methods recommended by the 2000 Report of the AVMA Panel on Euthanasia. The methods used most by the USM Animal Facility will be CO₂ asphyxiation, and anesthetic overdose. Any AVMA-approved method of euthanasia can be used, but all methods must be named in any protocol and approved by the IACUC Committee.

X. Animal Disease Agents

A. Disease Agents That Can Affect Research Results

Rodent disease agents may impact the animals, the personnel in contact with them, and the research. It is the policy of the University of Southern Maine to attempt to maintain an uninfected rodent population to protect the animals' health and welfare, and minimizes animal morbidity and/or mortality. Some organisms that infect rodents may be transmitted to humans, thus maintaining a disease free colony increases personnel safety. In addition, infection of a rodent colony may affect research results, because an infection that does not cause illness may act as an uncontrolled variable in many biological functions, including, but not restricted to, physiology, metabolism, and the immune system.

New agents may be introduced to USM facilities. There are frequent shipments of rodents onto campus. Most of these rodents come from approved sources with a low risk of carrying infection, such as commercial vendors that practice continuous health status monitoring and protective housing and management standards. Because of the low risk, these animals are assumed to be clean and are allowed into animal rooms without a quarantine period. However, some risk remains.

Rodents that originate from other research institutions, may carry more risk because the health monitoring program, husbandry, and management at other institutions cannot be verified as comparable to those of the commercial vendors. The health status of these animals is investigated, and if it appears likely that they are free of infectious agents, they are allowed onto campus under quarantine with further testing, either within the animal facility or in a satellite room. See Animal Facility Standard Operating Procedures for more information about the specifics of receiving or transporting animals.

B. Use of Selective Disease Agents in Research

Some research designs may call for the use of specific disease agents under strictly controlled conditions. Prior to designing this type of methodology, researchers must consult with the USM Attending Veterinarian and Animal Facility Manager to discuss the feasibility and impact the disease agents may have on the Animal Program. Prior to using disease agents in live animals, all researchers must seek Institutional Biosafety Approval or exemption from the Office of Research Compliance.

XI. Administrative Support of Animal Care and Use

A. Administrative Support (Staffing) of IACUC

The Office of Research Compliance (ORC) will provide administrative support to the IACUC that is proportional to proposal volume including an administrative assistant and IACUC analyst(s) who provide general staffing services and application screening, and an administrative coordinator to oversee operations of the IACUC. As part of its general staffing duties, the ORC will prepare and maintain records of

IACUC activities for at least 3 years and records related to protocols for at least 3 years after the completion/termination of the research. All records will be accessible to OLAW or PHS representatives within a reasonable time and manner as required by law, regulation or agency policy. The ORC will keep written IACUC records of the following items;

1. A copy of the PHS Assurance (if applicable);
2. Records of all animal proposals, proposed significant modifications and IACUC actions governing these documents;
3. Minutes of the IACUC meetings in sufficient detail to show attendance, actions taken at the meeting and votes on actions, the basis for requiring changes in research, and a summary of the IACUC discussion of controverted issues and their resolution;
4. Records of protocol review and continuing review activities;
5. Copies of all correspondence between the IACUC or its designee and animal users;
6. A list of IACUC members and their qualifications for serving on the board;
7. Written animal care and use procedures;
8. Records of semiannual IACUC review and recommendations forwarded to the Institutional Official;
9. Records of accrediting body determinations;
10. Any Reports to the Federal Office of Laboratory Animal Welfare, the Office of Research Integrity, or the US Department of Agriculture.

B. Animal Use Administrator

The Director of the Office of Research Compliance is the institutional agent for USM who exercises operational responsibility, on a day-to-day basis, for the institution's program for protection of animals. The Director should be contacted for comprehensive information regarding all aspects of USM's protections of human research subjects.

C. Communicating Adverse Events

The Director for the Office of Research Compliance or the IACUC chair must be contacted if any adverse animal events occur.

D. Policy Updates

The Director of the Office of Research Compliance is responsible for consulting the IACUC on required updates in University Policy and procedures regarding animals as new laws and regulations are promulgated or in accordance with DHHS Agent's requests or guidelines, or as needed to execute the USM Assurance or to meet University of Maine System Policies.