

SALEM STATE UNIVERSITY
Institutional Animal Care and Use Committee (IACUC) Policy

1.0 Purpose:

Salem State University recognizes the necessity of oversight of programs using animals in teaching and research. In the spirit of compliance with requirements set forth by the US Government in the Health Research Extension Act of 1985 (HREA) and the Animal Welfare Act (AWA), last amended in 1990, Salem State University has convened an Institutional Animal Care and Use Committee (IACUC).

This policy establishes criteria for the composition and conduct of business by the IACUC. The IACUC is responsible for developing and implementing procedures that will meet the requirements of this policy. Assurance that this policy is in place will be the responsibility of the Provost or designee.

1.1 Definitions:

This document defines “animal” as any live vertebrate animal protected by state and federal law and regulations. “Animal care and use facilities” are any buildings, rooms, areas structures or vehicles designed to confine, maintain, transport or use animals.

2.0 Scope:

This policy applies to faculty, undergraduate and graduate research including teaching protocols at SSU. The minimal standards for the IACUC should be based upon the following regulations and guidelines established by the following agencies:

Animal Plant Health Inspection Service (APHIS)

Animal Plant Health Inspection Service, USDA US Department of Agriculture

Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH)

Division of Marine Fisheries, Commonwealth of Massachusetts

Massachusetts Fish and Wildlife American Fisheries Society, Fish Culture Section. 2011. Guide to Using Drugs, Biologics, and Other Chemicals in Aquaculture. Bethesda, MD. 61pp. <http://www.fishculturesection.org/> accessed 16 January 2012.

Flimlin, G., S. Macfarlane, E. Rhodes, and K. Rhodes. 2010. Best Management Practices for the East Coast Shellfish Aquaculture Industry. U.S. Department of Agriculture, http://www.nrac.umd.edu/files/ECSGA_BMP_Manual.pdf, accessed 18 January 2012

Hollingsworth, C.S. R. Baldwin, K. Wilda, R. Ellis, and S. Soares. 2006. Best Management Practices for Finfish Aquaculture in Massachusetts. UMass Extension Publication AG-BPFA. 54pp.

Nickum, J.G., H.L. Bart Jr., P.R. Bowers, I.E. Greer, C. Hubbs, J.A. Jenkins, J.R. MacMillan, J.W. Rachlin, J.D. Rose, P.W. Sorensen and J.R. Tomasso. 2004. Guidelines for the Use of Fishes in Research. American Fisheries Society, Bethesda, MD. 56 pp.

USDA website, Approved Drugs for Aquaculture

<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/Aquaculture/ucm132954.htm>; accessed 21 January 2012

3.0 IACUC Composition:

3.1 IACUC composition will comply with the AWA, and the HREA.

3.2 The IACUC must have at least 5 members.

3.3 The IACUC members shall be appointed every year by the President or designee as described in NIH #85-23 *Guide for the Care and use of Laboratory Animals, (The Guide)* revised in 1985 and any succeeding revisions.

3.3.1 Membership appointments will begin September 1; the term of membership shall be staggered 2 year terms.

3.4 IACUC composition shall include:

3.4.1 A veterinarian who has training in laboratory animal medicine, has direct or delegated program authority, and is responsible for activities involving animals at the institution.

3.4.2 One member of the public (non-affiliated member) who must:

- Be unaffiliated with the institution
- Not be a member of the direct family of a person affiliated with the institution
- Be a non-laboratory user
- Be a representative of the general public
- Be reimbursed for expenses incurred. A modest honorarium may be provided, but should not be construed as compensation for services provided

3.4.3 A scientist who is currently engaged in practicing research involving animals

3.4.4 A non-scientist whose primary concerns are in a non-scientific area (e.g. ethicist, lawyer, clergy).

3.5 No more than three members may be from the same administrative unit

3.6 Representation on the IACUC from Regulatory, Compliance and/or Public Affairs office is encouraged

3.7 The President or designee may appoint two community or non-affiliated members.

3.8 The Chair of the IACUC will be of sufficient stature to perform the functions of

this position without jeopardy to his or her career.

3.9 Appointment of alternate members to the IACUC is acceptable.

3.9.1 Alternate members must be formally appointed by the President or designee.

3.9.2 There must be a specific one-to-one designation of alternate to member.

3.10 In accordance with *The Guide* all members must complete training and receive a certificate of completion once every three years from the CITI Program's "IACUC Chairs, Members, and Coordinators" or an equivalent training module.

3.11 No IACUC member may participate in the approval or review of an activity in which that member may have a conflicting interest. An IACUC member may participate in and provide technical guidance for the discussion of an activity in which the member may have a conflicting interest, but cannot participate in the decision-making process or be present for any IACUC vote on that activity.

4.0 Functions of the SSU IACUC:

4.1 The IACUC will perform all functions in compliance with relevant federal laws, regulations, policies, and guidelines relevant to the functioning of IACUCs as described below.

4.2 The IACUC must review at least once every six months, the site's program for the humane care and use of animals, using *The Guide* and title 9, chapter 1, subchapter A-Animal or the *Guidelines for The Use of Fishes in Research (2002)* Welfare of the Code of Federal Regulations (9 CFR. 1 A parts 1-4) as a basis for evaluation. Program review must include the following aspects:

4.2.1 IACUC membership and function

4.2.2 IACUC records and reporting requirements

4.2.2.1 Reports to Office of Laboratory Animal Welfare (OLAW) (as appropriate)

4.2.2.2 Reports to the U.S. Department of Agriculture (USDA) (as appropriate)

4.2.3 Veterinary care

4.2.3.1 Preventative medicine

4.2.3.2 Surgery

4.2.3.3 Pain, distress, analgesia, and anesthesia

4.2.3.4 Euthanasia

4.2.3.5 Drug storage and control

4.2.4 Personnel qualifications and training

4.2.5 Occupational health and safety program

4.3 The IACUC must inspect, at least once every six months, the site's animal facilities, using the *Guide (specify) or the Guidelines for The Use of Fishes in Research (2002)* and 9 CFR. 1 A parts 1-4 as a basis for evaluation.

4.3.1 An animal facility is one in which animals are housed for longer than 12 hours.

4.3.2 Areas in which surgical manipulation occur must always be inspected.

4.3.3 Inspections should evaluate: (Additional information is provided in the IACUC Semiannual Evaluation Guidance Documents.)

4.3.3.1 Animal husbandry

4.3.3.2 Veterinary care

4.3.3.3 Pest control and sanitation

4.3.3.4 Storage

4.3.3.5 Personnel and safety including disaster and emergency

4.3.3.6 Environment and facilities

4.3.3.7 Procedures

4.4 The IACUC must prepare a report of this semi-annual review and inspection and submit it to the President or designee.

4.4.1 The report must distinguish significant deficiencies from minor deficiencies.

4.4.1.1 The Animal Welfare Act (AWA) defines a significant deficiency as one which is or may be a threat to the health and safety of animals.

4.4.1.2 The IACUC may find deficiencies which they would not consider minor but which are not deemed to be a threat to the health and safety of animals. These may be problems which represent human health hazards, repetitive or chronic problems, problems which have been seen frequently in the inspection or problems that have been previously cited by regulatory bodies. These findings should be categorized using additional terms to indicate the appropriate level of severity without misusing the legal definition of 'significant'. The definition of a significant deficiency, as defined by the AWA, is a deficiency which ". . . in the judgment of the IACUC and the President or designee, is or may be a threat to the health or safety of the animals."

4.4.1.3 The IACUC might also identify areas of the animal care and use program where improvement would be desirable to further the institutional and corporate goals for a strong animal care and use program. These may be categorized as suggestions for improvement.

4.4.2 The report must contain a reasonable and specific plan and schedule with dates for correcting each deficiency.

4.4.2.1 If a significant deficiency remains uncorrected beyond the scheduled correction date, this deficiency shall be reported, by the IACUC, through the President or designee, within 15 business days, to

the Animal Plant Health Inspection Service (APHIS) (for USDA-regulated species), Office of Laboratory Animal Welfare (OLAW), and any federal agency funding that activity.

4.4.2.2 Suggestions for improvement do not require a written specific plan and schedule for correction but status should be noted in the next semiannual inspection.

4.4.3 The report must specifically identify any departures from the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) or 9 CFR 1 A parts 1-4 or the *Guidelines for The Use of Fishes in Research (2002)*, and state reasons for each departure.

4.4.4 This report must contain any minority views.

4.4.5 This report must be signed by a majority of members of the IACUC.

4.4.6 This report shall be submitted within 45 days of the end of the inspection process.

4.5 The IACUC shall make recommendations to the President or designee regarding any aspects of the animal care program, facilities, or personnel training.

4.6 The IACUC shall review, and if warranted, investigate concerns involving the care and use of laboratory animals.

4.7 By its affiliation as a state university of the Commonwealth of Massachusetts, the IACUC shall comply with the Commonwealth of Massachusetts Public Records Law Chapter 66 Section 10 of Massachusetts General Laws.

4.8 The IACUC shall review those components of proposed activities related to the care and use of animals.

4.8.1 Activities related to the care of animals should be presented to the IACUC as Standard Operating Procedures. Activities related to the use of animals in research, teaching or testing should be presented to the IACUC on the Animal Protocol Form.

4.8.2 The IACUC may approve, require modification, or withhold approval of proposed activities.

4.8.3 Review of all activities is required yearly.

4.8.4 Certain proposed animal activities should be considered for full committee review. These include:

4.8.4.1 Campus-wide training proposals

4.8.4.2 Invasive methods proposals

4.8.4.3 Process proposals

4.8.4.4 Proposals involving prolonged restraint of conscious animals

4.8.5 Certain proposed animal activities must go to full committee or designated member review.

4.8.5.1 Any proposal with a prospective unrelieved pain or distress

4.8.5.2 Proposals involving multiple major survival surgeries.

4.8.6 For all other activities, designated review, in which a reviewer(s) designated by the IACUC Chair or IACUC administrator gives approval to a proposed activity related to the care and use of laboratory animals, is an acceptable means of review.

4.8.7 The IACUC administrator must assure that IACUC members have adequate opportunity to request full committee review.

4.8.7.1 Members should be given at least five working days after distribution of the proposed animal activity to the IACUC to respond. This time should be allowed even if a quorum of responses has been received.

4.8.7.2. Unless a member specifically requests full committee review, the proposal can be reviewed and approved using the designated review process. (i.e., - no response is considered a tacit approval for the designated review process).

4.8.8 At any time, any member shall be able to call for full committee review of a proposed activity related to the care and use of laboratory animals.

4.8.9 The IACUC shall review new animal-related standard operating procedures (SOPs) before they are implemented or when substantial changes are made that affect the care and use of animals.

4.8.9.1 A subcommittee may be constituted to review SOPs on a schedule, such as during the semi-annual program review or on as needed basis. This subcommittee should include at least two IACUC members.

4.8.10 The IACUC may also develop a series of recommended guidelines for animal-related procedures to which all users must adhere. Any departure from those guidelines that may result in more pain or distress in animals requires the applicant to provide scientific justification for that deviation.

4.9 The IACUC shall review proposed significant changes regarding the care and use of animals in ongoing activities.

4.9.1 The IACUC must be notified in writing by the Principal Investigator when any approved animal activity is changed.

4.9.1.1 Changes may be minor or significant.

4.9.2 Minor changes in animal activities may be approved by a pre-assigned designated administrative reviewer.

4.9.3 The IACUC may approve, require modification, or withhold approval of proposed significant changes.

4.9.3.1 Significant changes must follow the same review process as a new submission.

4.9.4 Significant changes include:

4.9.4.1 Changes in objectives of the study

4.9.4.2 Changes in key personnel

4.9.4.3 Changes in anesthesia, analgesia, and/or euthanasia methods

4.9.4.4 Changes which increase the potential for animal pain or distress

4.9.4.5 Change in species

4.9.4.6 An increase in animal numbers with a 75% cap.

4.9.4.7 Major* changes in surgical procedures or other invasive procedures (*as determined by the veterinarian or IACUC chair)

4.9.4.8 Sampling frequencies, sampling volumes, restraint times, or other procedures deviating from approved SOPs or IACUC guidelines so as to possibly cause an increase in pain or distress.

4.9.4.9 Extension of study if such extension increases the potential for pain and distress of the animals.

4.10 The IACUC shall be authorized to suspend an activity involving animals in accordance with specifications in IV.C.6 of PHS Policy.

4.10.1 This action may only be taken after review of the matter by a convened meeting of a quorum of the IACUC and a vote for suspension by a majority of members present.

4.10.2 The President or designee, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action within 14 days with a full explanation to OLAW, APHIS, and any federal agency funding that activity.

4.10.3 The IACUC must also report to OLAW any serious or continuing noncompliance with PHS policy or serious deviations from the *Guide or the Guidelines for The Use of Fishes in Research (2002)*.

4.10.4 An authorized institutional representative, such as the chair of the IACUC, is urged to contact the appropriate regulatory agencies verbally with a preliminary report of incidents of serious noncompliance as soon as possible and follow up with a thorough report once action has been taken.

5.0 Training Requirements

5.1 All personnel involved in animal care, treatment, and/or use must be trained to insure that several key concepts related to responsible care and use of animals are fully understood including but not limited to:

- State, local, and federal regulations related to animal care and use
- SSU policies and procedures regarding animal care and use and facility operations
- Occupational health and safety issues and zoonoses
- Proper use of anesthetics, analgesics, etc. to minimize pain and distress for the animals
- Instruction in aseptic surgical techniques
- Guidelines for endpoints and euthanasia
- Guidelines for alternatives to animal use, methods to reducing the number of animals used, and unnecessary duplication of studies

The CITI Program's training modules "Investigators, Staff and Students", "Working with Rats in Research Settings", and "Working with Fish in Research Settings" fulfill federal training requirements. Any personnel including faculty, staff, students, technicians and/or principal investigators who work in an animal care laboratory must complete the appropriate training modules according to their discipline.

5.2 All faculty, staff, students, and researchers that use chemicals and/or generate hazardous waste must obtain Environmental Health and Safety (EHS) laboratory safety training. Certification must be kept current to work in any SSU laboratory. It is the responsibility of the faculty member or laboratory technician that oversees the laboratory to ensure that all workers complete the Environmental Health and Safety laboratory safety training and maintain certification. The CITI Program's Biosafety and Biosecurity training program fulfills federal training requirements.

5.3 The Principle Investigator tracks all training events and reports the type of training offered and the participants that have successfully completed the training. The Principle Investigator also maintains these records for inspection. The IACUC will review these records semiannually during their inspections.

6.0 Noncompliance Policy

6.1 Salem State University must review and if warranted, investigate all concerns involving the care and use of animals. All complaints must be reviewed but not all complaints may need to be investigated. Protocol noncompliance occurs when procedures or policies affecting animal care or use are not followed. When faced with protocol noncompliance, the institution will work to bring the protocol into compliance or take immediate action to stop any mistreatment of animals. The appointed animal care review committee shall be empowered to make a decision as to the type of violation and suspend any research or teaching activity if it finds violations that are a threat to the health or safety of animals or activities conducted that are not in accordance with provision of the Animal Welfare Act, the Guide for the Care and Use of Laboratory Animals, or the Salem State University Assurance. The committee may suspend activity and/or make a decision as to the type

of disciplinary action recommended and make such recommendations or consult with the Institutional Official to impose further sanctions. The attending veterinarian also has the authority to suspend an activity to provide adequate veterinary care and the Institutional Official will be quickly notified so that a committee may be appointed and the event reviewed.

6.2 Any and all violations require prompt response to resolve the problem that initiated the violation. All incidents are entered into the animal care log and reported to the attending veterinarian, IACUC, and Institutional Official.

7.0 IACUC Meetings:

7.1 The IACUC must meet at least semi-annually.

7.2 A quorum, defined as greater than 50% of voting members, must be present for a meeting to be considered a convened meeting.

5.2.1 A convened meeting is able to conduct full committee review of a research project and/or suspension of an activity.

7.3 Guests may be invited to IACUC meetings at the discretion of the Chair and members.

7.4 Minutes of the meeting will be kept.

7.5 Minutes will either be circulated for review and signature or approved at the subsequent meeting.

7.6 Meeting minutes will reflect when an item or issue is opened, and when it is resolved or closed.

7.7 Recommended standard agenda items are listed in Appendix A.

8.0 IACUC records

8.1 The IACUC administrator will be responsible for maintenance of IACUC-related records. IACUC-related records include:

8.1.1 IACUC meeting minutes

8.1.1.1 Minutes will include activities, and deliberations

8.1.1.2 Minutes of deliberations should not include who said what, research staff names or other information deemed confidential.

8.1.2 Semi-annual reports

8.1.3 All documents related to the review of research projects and SOPS

8.1.4 PHS Assurance documents

8.1.5 USDA research registration or dealer license if applicable

8.1.6. Permits from the MA Division of Marine Fisheries and Division of Fisheries and Wildlife make edit and include Mass Fish and Wildlife

8.1.7 Records of accrediting body determinations if applicable

8.2 Records must be kept for three years after the end of animal-related work or as required by relevant regulations.

8.3 Records related to applications, proposals, and proposed significant changes must be kept for the duration of the activity, plus three years or as required by relevant regulations.

References:

Animal Welfare Act

Animal Welfare Regulations (9 CFR 1 A parts 1-4)

Good Laboratory Practice Regulations (21 CFR Part 58; 40 CFR Parts 160,792)

Guide for the Care and Use of Laboratory Animals

Guidelines for The Use of Fishes in Research (2002)

Health Research Extension Act of 1985

Public Health Service Policy on Humane Care and Use of Laboratory Animals Institutional Animal Care and Use Committee Guidebook

Appendix A Guidance for IACUC meetings

The agenda of an IACUC meeting should include, but is not limited to, the following items. Items opened at a meeting should be closed or have a completion or resolution date recorded in the minutes.

- Attendance
- Must have a quorum to conduct business
- Record visitors, guests
- Approval of the last meeting's minutes
- Solicit corrections to minutes
- Protocol review
- Committee deliberations must include enough detail in summary to be able to reconstruct discussion
- Does not need to include exactly who said what
- Will be a public document; do not include sensitive or proprietary information
- Semi-annual inspection deficiencies or concerns still outstanding
- Do not include semi-annual reports as part of regular IACUC meeting minutes. Animal welfare concerns
- SOP review
- Maybe review of new SOPs
- Maybe yearly review of established SOPs
- These should be SOPs that concern animal care or have a direct impact on animals.
- Items from laboratory research technicians or supervisors
- Safety concerns

Subcommittee reports

Training (of the IACUC)