

ANIMAL CARE AND USE PROGRAM

Institutional Animal Care and Use Committee



ST. CLOUD STATE
U N I V E R S I T Y™

Animal Care and Use Program

Policies, procedures, standards, organizational structure, staffing, facilities and practices put into place by St. Cloud State University for the humane care and use of animals in the laboratory and throughout the university.

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CONTENTS

Preamble	2
1. Animal Care and Use Program Oversight	2
2. Disaster Planning and Emergency Preparedness	2
3. Institutional Animal Care and Use Committee	3
4. IACUC Protocol Review – Special Considerations	3
Endpoints.....	4
Physical Restraint and Alternatives	4
Multiple Surgical Procedures	4
5. IACUC Membership and Functions.....	4
Membership Requirements.....	5
Semi-Annual Reporting.....	5
Concern or Complaint Reporting.....	5
Protocol Review Procedure	5
Holding Protocols	6
Full Committee Review.....	6
Designated Member Review	6
Minor Changes	7
Significant Changes.....	7
Continuing Review/Final Report	7
Activity Suspension.....	8
Exemption from Multiple Survival Surgery Restrictions	8
6. IACUC Training.....	8
Training Learner Groups.....	8
7. IACUC Records and Reporting Requirements	9
Satellite Facilities.....	9
Protocol Exceptions.....	9
USDA Reporting.....	9
Recordkeeping.....	10
8. Veterinary Care.....	10
9. Personnel Qualifications and Training.....	11
10. Occupational Health and Safety of Personnel.....	11
11. Personnel Security.....	11
Animal Facility Access.....	11
12. Investigating and Reporting Animal Welfare Concerns	12
13. Definitions	13

ANIMAL CARE AND USE PROGRAM

PREAMBLE

The Institutional Animal Care and Use Committee (IACUC) of St. Cloud State University (University) is responsible for overseeing the use of live vertebrate animals (herein referred to as animal or animals) and animal facilities and for the review of basic science and biomedical research and teaching activities involving animals conducted at, or in association with, St. Cloud State University. The IACUC ensures animal care and use is in compliance with applicable federal, state and local regulations as well as University policies and assurances. The basis of compliance is determined by the United States Department of Agriculture Animal Welfare Act and Animal Welfare Regulations (AWAR), the Institute for Laboratory Animal Research's (ILAR) *Guide for the Care and Use of Laboratory Animals* (Guide), the *Guide for the Care and Use of Agriculture Animals in Research and Teaching*, the Public Health Service (PHS) Policy on the Care and Use of Laboratory Animals and other applicable regulations.

1. ANIMAL CARE AND USE PROGRAM OVERSIGHT

Primary oversight responsibilities of the animal care and use program rest with the institutional official, the attending veterinarian and the IACUC. Together they establish policies and assurances, ensure regulatory compliance, monitor program performance and support basic science and biomedical research and teaching activities involving the use of animals. The IACUC is responsible for review, evaluation and oversight of all laboratory-based and field-based animal use activities, including pilot studies, occurring on campus and/or utilizing University facilities or equipment. All committee members share in these responsibilities. The IACUC reserves the right to defer to legal counsel related to the applicability of policies and procedures.

The Associate Provost for Research serves as the institutional official and bears the ultimate responsibility for the program. The institutional official is responsible for resource planning and ensuring the alignment of program goals of quality animal care and use with the University's mission. The institutional official will ensure resources are available as needed to manage the program and training component in accord with federal regulations. The attending veterinarian and the IACUC will communicate regularly with the institutional official related to program needs.

The attending veterinarian is responsible for the health and well-being of all laboratory animals used at the University and works in collaboration with the vivarium manager related to animal husbandry and housing to ensure compliance with federal regulations. Resources are available for consultative veterinary services provided at intervals appropriate for program needs. The vivarium manager is responsible for the daily animal care and facility management of the majority of animal holding spaces at the University.

2. DISASTER PLANNING AND EMERGENCY PREPAREDNESS

Animal facilities may be subject to unexpected conditions which result in the catastrophic failure of critical systems or significant personnel absenteeism or other unexpected events that severely compromise ongoing animal care and well-being. Regularly used animal facilities of the University shall have a disaster

plan clearly posted in the animal facility. The plan shall include policies or procedures for ensuring safety of personnel and animals, response plans to address major system failures and contact information for the animal facility manager, applicable IACUC members, research faculty, emergency responders or any other stakeholders. The plan should define the actions necessary to prevent animal pain, distress and deaths due to loss of systems such as those that control ventilation, cooling, heating or provision of potable water. If possible, the plan should describe how the facility will preserve animals that are necessary for critical research activities or are irreplaceable. Animals that cannot be relocated or protected from the consequences of the disaster must be humanely euthanized. Disaster plans should be established in conjunction with the responsible investigator(s), taking into consideration both the priorities for triaging animal populations and the University needs and resources. All disaster plans and subsequent updates must be approved by the IACUC.

3. INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

The IACUC is responsible for the oversight and evaluation of the entire program. Its oversight functions include review and approval of proposed animal care and use protocols and proposed significant changes to animal care and use; semi-annual inspection of facilities and animal use areas; semi-annual review of the program; ongoing assessment of animal care and use; and establishment of a mechanism for receipt and review of concerns involving the care and use of animals at the University. To provide such oversight, the IACUC shall meet once per month during the academic year or as often as necessary throughout the year to fulfill its responsibilities.

Since some IACUC members are practicing scientists, IACUC members named in protocols or who have other conflicts of interest in a specific protocol must recuse themselves from the protocol approval process, except to provide any information requested by the IACUC during the review process.

Continuing IACUC oversight of animal activities is required by federal laws, regulations and policies. Protocols can initially be approved for one year with up to two one-year renewals if a Continuing Review Report is timely filed with the IACUC and approved. After three years or when the project is complete, whichever comes first, a final report should be filed with the IACUC. In addition, post approval monitoring shall be facilitated via semi-annual facilities inspection; veterinary or IACUC observation of selected procedures; observation of animals by animal care staff, attending veterinarian, applicable University personnel and students, and IACUC members; or external regulatory inspections and assessments.

All personnel involved with the care and use of animals must be adequately educated, trained and/or qualified in basic principles of laboratory animal science to help ensure high-quality science and animal well-being. The institutional official is responsible for providing appropriate resources to support personnel training and the IACUC is responsible for providing oversight and for evaluating the effectiveness of the training program. All program personnel training should be documented.

4. IACUC PROTOCOL REVIEW – SPECIAL CONSIDERATIONS

Certain animal care and use protocols may include procedures or approaches that require special consideration during the IACUC review process due to their potential for unrelieved pain or distress or other animal welfare concerns. The IACUC will weigh the objectives of the study against potential animal welfare concerns. By considering opportunities for refinement, the use of appropriate non-animal

alternatives and the use of fewer animals, the University and the principal investigator address their shared obligations for humane animal care and use.

ENDPOINTS

The experimental endpoint of a study occurs when the scientific aims and objectives have been reached. The humane endpoint is the point at which pain or distress in an experimental animal is prevented, terminated or relieved. The use of humane endpoints contributes to refinement by providing an alternative to experimental endpoints that result in unrelieved or severe animal pain and distress, including death, and should be relevant and reliable. While all studies should employ humane endpoints, special consideration will be given to studies that involve tumor models, infectious diseases, vaccine challenge, pain modeling, trauma, production of monoclonal antibodies, assessment of toxicologic effects, organ or system failure and models of cardiovascular shock. The principal investigator, who has precise knowledge of both the objectives of the study and the proposed model, should identify, explain and include in the animal use protocol a study endpoint that is both humane and scientifically sound.

PHYSICAL RESTRAINT AND ALTERNATIVES

Physical restraint using manual or mechanical means to limit some or all of an animal's normal movement for the purpose of examination, collection of samples, drug administration, therapy or experimental manipulation will be justified in animal use protocols. Restraint devices should be suitable in size, design and operation to minimize discomfort, pain, distress and the potential for injury to the animal and the research staff. When restraint devices are used, they should be specifically designed to accomplish research goals that are impossible or impractical to accomplish by other means or to prevent injury to animals or personnel. Animal use protocols involving physical restraint shall include considerations for alternatives to physical restraint, period of restraint is the minimum required to accomplish the scientific objectives and training of animals, with positive reinforcement, to adapt to restraint equipment is provided. Animals that do not adapt to necessary restraint systems should be removed from the study. The IACUC shall determine the appropriate observation intervals of restrained animals. Veterinary care must be provided if lesions or illnesses associated with restraint are observed. The purpose of the restraint and its duration should be clearly explained to personnel involved with the study.

MULTIPLE SURGICAL PROCEDURES

Surgical procedures in the laboratory setting may be categorized as major or minor and should be evaluated on a case-by-case basis by the veterinarian and the IACUC. Multiple surgical procedures on a single animal must be justified by the principal investigator and the outcomes evaluated by the IACUC to determine the impact on the animal's well-being. Multiple major surgical procedures on a single animal are acceptable only if they are included in and essential components of a single research project or protocol, scientifically justified by the investigator or necessary for clinical reasons. Justifications for allowing animals not regulated by the USDA to undergo multiple survival procedures that meet the above criteria shall conform to those required for regulated species (refer to IACUC Membership and Functions section).

5. IACUC MEMBERSHIP AND FUNCTIONS

The IACUC must be sufficiently qualified through the experience, expertise and diversity of its members to maintain oversight of the University's animal care and use program, facilities and procedures to provide complete and adequate review of all animal activities conducted in teaching or research through the University. The IACUC shall have the authority and resources for oversight and evaluation of the

University's program. Members of the IACUC are appointed by the institutional official on behalf of the President of St. Cloud State University per requirements of Public Health Services Policy IV.A.3. and the National Research Council of the National Academies *Guide for the Care and Use of Laboratory Animals* and shall consist of no less than five voting members, including at least:

- one Doctor of Veterinary Medicine with training and experience in laboratory animal medicine
- one practicing scientist experienced in research involving animals
- one member whose primary concerns are in a nonscientific area
- one public member to represent general community interests in the proper care and use of animals, who is not affiliated with the University in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the University

MEMBERSHIP REQUIREMENTS

An individual who meets the requirements of more than one of the categories may fulfill more than one requirement. However, the committee will not consist of less than five members. The IACUC also includes individuals serving in an advisory capacity based on their experience in laboratory animal science (vivarium manager) or higher education administration (IACUC administrator). A quorum is met when more than 50% of the voting members participate. To remain a member and have voting rights, members must complete the IACUC member training, participate in the review of protocols and programs, and attend at least 50% of the meetings held during the academic year.

SEMI-ANNUAL REPORTING

At least once every six months, the IACUC will review the Animal Care and Use Program, review the Veterinary Care Program and inspect all of the University's animal facilities (including satellite facilities, if applicable), using the *Guide* as the basis for evaluation. After review and inspection, the IACUC will provide a written report, including any minority views, to the institutional official about the status of the programs and animal facilities. Reports shall be maintained by the University and made available to the Office of Laboratory Animal Welfare upon request. Reports will include a description of the nature and extent of the University's adherence to the *Guide* and PHS Policy, identify specifically any departures from these provisions and state the reasons for the departure. Reports will also distinguish significant deficiencies from minor deficiencies. Program or facility deficiencies noted must contain a reasonable and specific plan and schedule for correcting each deficiency.

CONCERN OR COMPLAINT REPORTING

Safeguarding animal welfare is the responsibility of every individual associated with the program. The University is committed to the humane treatment of all animals used in research and teaching activities. The privilege to use animals for the advancement of science and medicine carries with it the responsibility to follow applicable laws, policies and procedures established to promote the well-being and ethical treatment of animals. Concerns or complaints regarding the care and use of animals at the University can be brought to the course instructor, principal investigator of the research project, any IACUC member, the IACUC administrator or the institutional official. Concerns can be communicated verbally or by completion of the Animal Care Concern Form. Mechanisms for reporting concerns and appropriate contact personnel will be included on the IACUC website and posted in regularly used animal facilities.

PROTOCOL REVIEW PROCEDURE

For the health and welfare of animals, the IACUC has the authority to review, approve, require modification in (to secure approval) and withhold approval of any animal care and use protocol or proposed minor or significant change to an existing protocol. The following is the procedure for protocol review:

- Principal investigator submits the completed animal care and use protocol to the IACUC administrator to initiate the review process, following the deadline for protocol submissions
- IACUC administrator contacts the attending veterinarian and vivarium manager for initial review of the protocol. About one week review time.
- IACUC vivarium manager provides their initial feedback, as well as the attending veterinarian feedback, to the principal investigator and copies the IACUC administrator and chairperson on the email communication. The principal investigator responds to changes either via email or an updated protocol. If significant changes, an updated protocol may be requested.
- IACUC administrator contacts IACUC members for review of the revised protocol; about one week review time.
- If time allows, IACUC chairperson provides committee feedback to principal investigator, and copies the IACUC administrator, who responds to changes either via email or an updated protocol. If significant changes, an updated protocol may be requested.
- IACUC administrator submits protocol to IACUC members for review (about one week review time) or the protocol is added to the agenda of the next IACUC meeting for review and/or approval; principal investigator may be asked to attend the meeting.

HOLDING PROTOCOLS

All animals housed at St. Cloud State University must be covered by an active and approved IACUC protocol. Circumstances may arise whereby animals held for a study are no longer covered by an IACUC approved protocol. As defined in the protocol, coverage of animals may initiate immediately upon expiration of an animal use protocol under which existing animals were previously covered, immediately upon suspension of an animal use activity or protocol by the IACUC or immediately upon receipt of animals for which an active animal use protocol does not exist. The principal investigator(s) for whom animals are being held must remedy the circumstances requiring use of the holding protocol before the animals may be transferred to an animal use protocol.

FULL COMMITTEE REVIEW

A majority vote of a quorum at a convened meeting is required for full committee approval of an animal care and use protocol. On an exception basis only, voting members may be present at convened meetings via phone or video conferencing. If a protocol requires modifications in order to secure approval, meeting minutes will reflect the required modifications and how the final approval will be made either through designated member review (designated member[s] review the principal investigator's responses and decide if full IACUC approval is warranted) or if full committee review at a convened meeting is required to review the requested modifications. Approval date is when all requested modifications have been made by the researcher and the designated member has reviewed and approved the modifications. University officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC. The committee's actions will be communicated to the principal investigator in writing.

DESIGNATED MEMBER REVIEW

The second acceptable method of protocol review is known as designated member review. Using this method, all IACUC members receive the proposed animal care and use protocol and attachments to be reviewed. If any member feels that this protocol should go before a full committee, then its review must be deferred to the next full IACUC meeting. Any member can make the decision to send the protocol to full committee review at any time during the one week time period allotted. If no member calls for a full committee review, then the IACUC chairperson refers the protocol in question to the designated reviewer(s) who will review the protocol in consultation with the attending veterinarian and possibly the

vivarium manager. The designated member(s) act on behalf of the entire IACUC to approve the protocol, request additional information from the principal investigator or refer the protocol for full review. If a research project involves procedures which cause more than momentary or slight pain or distress to any of the animals in the study, the attending veterinarian must be consulted prior to approval of the protocol. The designated-reviewer approval has equal validity to full committee review approval and does not require subsequent re-approval or notification by a convened meeting. It is always possible for the IACUC to discuss protocols approved by either method in future meetings as a form of continuing review or in response to animal welfare concerns. A designated reviewer does not have the power to withhold approval and must, in such cases, refer the protocol for full committee review.

MINOR CHANGES

Minor changes to an approved protocol may be requested using the Change in Protocol Form. Minor changes to existing protocols may include but are not limited to:

- Addition of co-investigator(s) or other investigator(s)
- Minor change in the duration, frequency or number of procedures performed on an animal
- Addition of minor surgery or procedure
- Need to repeat an approved experiment
- Increase of $\leq 10\%$ in the number of animals needed in a particular experiment
- Addition of a different strain or gender of an approved animal species
- Change in animal housing (but still within standard methods)
- Change in experimental treatment compound
- Substitution of qualified students/technicians or addition of investigative collaboration (does not include changes in principal investigator)

SIGNIFICANT CHANGES

Significant changes require the submission of a new protocol for review and approval. Final determination of whether the change is minor or significant will be made by the IACUC and may follow either the full committee or designated member review process. Significant changes to existing protocols may include but are not limited to:

- Change in principal investigator
- Change in study objectives
- Significant change in the duration, frequency or number of procedures performed on an animal
- Increase in the degree of invasiveness of a procedure or discomfort to an animal
- Change from non-survival to survival surgery
- Increase in animal numbers $>10\%$
- Change or addition of species
- Change in anesthetics or analgesics
- Change in method or agent of euthanasia
- Change in criteria for humane end-point
- Change in animal housing, care and/or feeding to non-standard method
- Addition of hazardous chemical or biological agents

CONTINUING REVIEW/FINAL REPORT

Protocols may be approved for up to one year with eligibility to extend on an annual basis for up to a three year period of time. Principal investigators will be required to submit an annual report if requesting a one year extension of the IACUC approved protocol since research continues but no changes have occurred or research continues and anticipated changes are outlined in the Change to Protocol form

attached to the extension request. Final reports should be submitted after the project has been completed or to provide notification that the study has not and will not occur. After three years has passed from initial approval, a new protocol will be required along with expectations the principal investigator will reconsider alternatives and update literature searches and justifications for animal use.

ACTIVITY SUSPENSION

The animal facility manager, attending veterinarian, institutional official or any IACUC member may immediately stop an animal use activity if any animals are being harmed or mistreated and the incident must be reported as soon as possible following proper IACUC procedure. The IACUC may suspend an activity it previously approved if it determines that the activity is not being conducted in accordance with the approved protocol, applicable provisions of the Animal Welfare Act, the *Guide*, the University's Assurance (if applicable) or PHS Policy. The activity in question is to be reviewed at a convened meeting of the IACUC where a quorum is present. If an activity is to be suspended, a majority vote of the quorum of members is required and the institutional official must be notified in a timely manner. After consulting with the IACUC, the institutional official will take the appropriate corrective action and report the incident and findings to the applicable federal agency, if necessary. The institutional official may pursue an investigation following the Policies and Procedures for the Handling of Allegations of Academic or Research Fraud and Serious Misconduct at St. Cloud State University.

EXEMPTION FROM MULTIPLE SURVIVAL SURGERY RESTRICTIONS

Conservation of scarce animal resources may justify the conduct of multiple major surgeries on a single animal, but the application of such a practice on a single animal used in separate protocols will be discouraged and reviewed by the IACUC. When applicable, the institutional official must submit a request to the USDA/APHIS and receive approval in order to allow a regulated animal to undergo multiple major survival surgical procedures in separate unrelated research protocols. If multiple survival surgery is approved, the IACUC shall pay particular attention to animal well-being through continuing evaluation of outcomes.

6. IACUC TRAINING

It is the University's responsibility to ensure IACUC members are provided with training opportunities to understand their work and role. Training will include an orientation to the program; relevant legislation, regulations, guidelines and policies; semi-annual evaluation process; performing the facility inspection and program review; and aspects of protocol review. Ongoing opportunities to enhance member understanding of animal care and use or changes to legislation, regulations, guidelines or policies may be provided. IACUC members must complete the required IACUC-Members training within sixty days of appointment to the committee and prior to providing guidance and/or voting on animal use protocols.

TRAINING LEARNER GROUPS

St. Cloud State University utilizes the Collaborative Institutional Training Initiative (CITI) Program to provide online training for the various learner groups. In coordination with Academic Affairs, the IACUC has determined specific learner groups and faculty can require any additional modules for their students as they deem appropriate for the humane care and use of animals. Learner groups are identified as:

- Faculty submitting protocols
- IACUC members
- Graduate student researchers

- Undergraduate student researchers
- Vivarium workers
- Students in class

7. IACUC RECORDS AND REPORTING REQUIREMENTS

The IACUC is responsible for oversight and evaluation of the entire program and its components. At least once every six months, the committee shall review the University's program for the humane care and use of animals and inspect all of the University's animal facilities (including satellite facilities, if applicable), using the *Guide* as a basis for evaluation. The resulting reports will contain a description of the nature and extent of the University's adherence to the *Guide* and PHS Policy and will identify specifically any protocol approved departures from the regulations and will state the reasons for each departure. The reports will distinguish significant deficiencies from minor deficiencies and include minority IACUC views. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Such reports will be submitted to the institutional official within a timely manner after their approval by the IACUC, maintained by the University and be made available to OLAW upon request.

SATELLITE FACILITIES

The University is responsible for oversight of all animal-related activities regardless of how long or where the activity occurs. Satellite facilities (defined by PHS Policy as a containment outside a core or centrally managed area in which animals are housed for more than 24 hours) and areas where any form of surgical manipulations (minor, major, survival, non-survival) are performed must be inspected at least once every six months by the IACUC as part of the semiannual evaluation. The University has discretion with regard to how it oversees areas used for routine weighing, dosing, immunization or imaging, but should monitor such areas on a random or fixed schedule to effectively oversee activities at the University. USDA requires semi-annual inspection of "animal study areas" defined as areas where USDA covered animals are housed for more than 12 hours.

PROTOCOL EXCEPTIONS

Exceptions to the standards and regulations requested in an animal care and use protocol will be specified and explained by the principal investigator. The IACUC will review such requests and may or may not grant approval. The principal investigator is responsible for responding to each question in the protocol which is applicable to their proposed activity. Considerations will include alternatives to procedures that cause more than momentary or slight pain or distress to the animals and has provided a written narrative description of the methods and sources used to determine that alternatives were not available. The principal investigator will provide written assurance activities do not unnecessarily duplicate previous experiments unless sufficient justification can be provided. The IACUC will ensure through their review process such responses are in alignment with federal regulations.

USDA REPORTING

When holding an active registration with the U.S. Department of Agriculture, annual reports will be filed containing required information, including all exceptions and exemptions. Where exceptions to the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Teaching are required, the decision will be made upon review by the IACUC. Such exceptions would not be made solely for the purposes of teaching or demonstration. IACUC-approved exceptions to the regulations and standards will be reported to the U.S. Department of Agriculture.

The schedule, as approved by the IACUC, for correcting facility significant deficiencies will be adhered to. Failure to do so will be reported in writing within 15 business days by the IACUC, through the Institutional Official, to the appropriate federal agencies. Animal care and use activities approved by the IACUC and suspended thereafter will be promptly reported to the U.S. Department of Agriculture and the appropriate federal funding agency.

RECORDKEEPING

The IACUC, in conjunction with the institutional official, shall ensure adequate recordkeeping of IACUC reviews, approvals and inspections. IACUC meeting minutes will include records of attendance, committee deliberations and approval decisions. Animal care and use protocols reviewed and approved by the IACUC, along with proposed and/or approved minor changes to the protocol, will remain on file with the University for the duration of the activity and for an additional three years after completion of the activity. IACUC minutes and semiannual reports to the institutional official will be retained on file with the University for three years. All such records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

8. VETERINARY CARE

Veterinary care is an essential part of an animal care and use program. The primary focus of the attending veterinarian is to oversee the well-being and clinical care of animals used in research, testing, teaching and production. This responsibility is in collaboration with the vivarium manager in monitoring and promoting animal well-being at all times during animal use and during all phases of the animal's life. The vivarium manager is responsible for the daily animal care and facility management, representing the majority of the University's regularly used animal holding spaces.

Veterinary services are provided on a consultative basis appropriate to meet program needs. The attending veterinarian will be a Doctor of Veterinary Medicine either certified (e.g. by ACLAM, ECLAM, JCLAM, KCLAM) or with training and experience in laboratory animal science and medicine or in the use of the species at the University. Backup veterinarian services should be in place as well. Formal arrangements include a written program of veterinary care; regularly scheduled visits to the University and its animal facilities; and availability via phone for consultative veterinary services. The University will provide the attending veterinarian with sufficient authority and access to all animals to provide oversight in the management of animal care and use.

Through initial review of protocols submitted, the attending veterinarian provides guidance to principal investigators to ensure appropriate animal husbandry, handling, medical treatment, immobilization, sedation, analgesia, anesthesia, euthanasia, surgery programs and perioperative care involving animals. Follow up is facilitated through discussion at IACUC meetings or communication by the vivarium manager, IACUC administrator, IACUC members or the institutional official. As a member of the IACUC, the attending veterinarian is intricately involved in animal care and use review, discussions and decisions.

Studies that may result in severe or chronic pain or significant alterations in the animals' ability to maintain normal physiology or adequately respond to stressors, should include descriptions of appropriate humane endpoints or provide science-based justification for not using a particular, commonly accepted humane endpoint. Veterinary consultation will occur when pain or distress is beyond the level anticipated in the protocol description or when interventional control is not possible.

9. PERSONNEL QUALIFICATIONS AND TRAINING

All personnel involved with the care and use of animals must be adequately educated, trained and/or qualified in basic principles of laboratory animal science to help ensure high-quality science and animal well-being. The institutional official, on behalf of the University, is responsible for providing appropriate resources to support personnel training and the IACUC is responsible for providing oversight and for evaluating the effectiveness of the training program.

Completion of the training modules for the applicable learner group(s) will be required for all University investigators, co-investigators and other investigators listed on a protocol before the protocol can be approved. In addition to the various learner group modules, standardized species specific training may be available. Faculty are encouraged to conduct procedure specific training with their students. Standard training modules are provided and documented through the Collaborative Institutional Training Initiative (CITI) program.

10. OCCUPATIONAL HEALTH AND SAFETY OF PERSONNEL

The University maintains an occupational health and safety program consistent with federal, state and local regulations. The University is committed to fostering a total safety culture which is a shared mind-set based on personal commitment where all believe performing their jobs safely is essential and is not in competition with personal or organizational priorities. Many policies, procedures and guidelines have been developed to address a variety of occupational safety and health issues. More information can be found on the University website at: <http://stcloudstate.edu/osh/occupational/default.aspx>.

11. PERSONNEL SECURITY

The University is committed to providing safe and secure environments in which students and faculty can engage in research and teaching activities, including those involving animals, without threat of harassment or assault. In order to ensure security in animal facilities, all requests for access must be reviewed and approved by the animal facility manager or, in his/her absence, the IACUC chairperson.

The following spaces are presently designated as animal facilities and the individual(s) in charge of these spaces are indicated below:

- ISELF 305–316B (Vivarium): Brian Lorenz or Maureen Tubbiola (alternate)
- WSB 9: Heiko Schoenfuss or Satomi Kohno (alternate)
- WSB 32: Heiko Schoenfuss or Satomi Kohno (alternate)
- WSB 291A–F (Aquatic Vertebrate Facility): Brian Lorenz or Maureen Tubbiola (alternate)

ANIMAL FACILITY ACCESS

Access to an animal facility will be either supervised or unsupervised. Individuals granted supervised access will not be issued a key, card-swipe privileges, door entry codes, or other means of accessing an animal facility independently. Supervised access is granted most commonly to students enrolled in a course in which animals are used as part of an IACUC-approved teaching activity. During such an activity,

either the animal facility manager or an individual named as a principal investigator on the IACUC-approved protocol covering the animal use activity must remain within the animal facility at all times while the students are present.

Supervised access may also include tours of an animal facility conducted by the animal facility manager or the principal investigator on an IACUC-approved protocol, as well as site visits by vendor representatives for the purpose of servicing or inspecting equipment or building systems within an animal facility. In all cases, individuals granted supervised access may not be left unattended within an animal facility, except at the discretion of the animal facility manager or IACUC chairperson.

Individuals granted unsupervised access will be issued of a key, card-swipe privileges, door entry codes, or other appropriate means of accessing an animal facility independently. Such access will be granted only to the following:

- individuals named on current IACUC-approved animal use protocols;
- student workers or research students whose primary responsibility is animal care;
- an animal facility manager;
- an animal facility manager's alternate contact
- the IACUC chairperson;
- an IACUC attending veterinarian;
- the IACUC administrator; or
- emergency contacts listed on the animal facility disaster plan.

Requests for access may be made by contacting the animal facility manager. If he/she is unavailable, the IACUC chairperson may be contacted. Individuals granted unsupervised access to an animal facility may not share keys, swipe cards, door entry codes, or any other means of access with others. *All means of unsupervised access are for the exclusive use of the individual to whom they are granted.* No University personnel may authorize access to an animal facility without contacting the animal facility manager or the IACUC chairperson.

In the event of an emergency, a reasonable effort must be made to contact the animal facility manager prior to entering an animal holding room. Building or equipment maintenance and repair occurring within or affecting an animal facility must be arranged in advance with the animal facility manager or IACUC chairperson.

12. INVESTIGATING AND REPORTING ANIMAL WELFARE CONCERNS

Concerns are to be communicated verbally or by completion of the Animal Care Concern Form. The concern, whether written or verbal, will be presented to the institutional official for review, possible informal or formal investigation, and/or appropriate action. Reported concerns and corrective actions will be documented. After consulting with the IACUC, the institutional official will take the appropriate corrective action and report the incident and findings to the applicable federal agency, if necessary. The institutional official may pursue an investigation following the Policies and Procedures for the Handling of Allegations of Academic or Research Fraud and Serious Misconduct at St. Cloud State University.

DEFINITIONS

Animal – Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes. This includes:

1. Any nonhuman vertebrate mammal at or beyond 50 percent of its gestational period;
2. All larval stages of fish and amphibians, but excludes their embryonated eggs; and
3. Viable embryonated eggs of birds and reptiles at or beyond 75 percent of their gestational period.

USDA regulations would only apply if the live vertebrate meets the USDA definition of animal: **Animal** means any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. This term excludes birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research; horses not used for research purposes; and other farm animals, such as, but not limited to, livestock or poultry used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs, including those used for hunting, security, or breeding purposes.

Animal Care and Use Program – is the policies, procedures, standards, organizational structure, staffing, facilities and practices put into place by the University to achieve the humane care and use of animals in the laboratory and throughout the University.

Animal facility – is any and all buildings, rooms, areas, enclosures or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.

Animal facility manager – is the individual responsible for a particular animal holding or use space.

Animal use – The proper care, use and humane treatment of laboratory animals produced for or used in research, testing or teaching.

Assurance – is the documentation from the University assuring University compliance with the Animal Welfare Act.

Attending veterinarian – is the veterinarian responsible for the health and well-being of all laboratory animals used at the University.

AWAR - United States Department of Agriculture **Animal Welfare Act Regulations** - The Animal Welfare Act was signed into law in 1966. It is the only Federal law in the United States that regulates the treatment of animals in research, exhibition, transport and by dealers. Other laws, policies, and guidelines may include additional species coverage or specifications for animal care and use, but all refer to the Animal Welfare Act as the minimum acceptable standard. The Act is enforced by the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care.

Guide – The purpose of the *Guide for the Care and Use of Laboratory Animals* is to assist institutions in caring for and using animals in ways judged to be scientifically, technically and humanely appropriate. The

Guide is also intended to assist investigators in fulfilling their obligation to plan and conduct animal experiments in accord with the highest scientific, humane and ethical principles.

Humane care – are those actions taken to ensure laboratory animals are treated according to high ethical and scientific standards.

IACUC - the Institutional **A**nimal **C**are and **U**se **C**ommittee is responsible for overseeing the use of animals and animal facilities and for the review of basic science and biomedical research and teaching activities involving animals conducted at, or in association with, the University.

ILAR – the Institute for **L**aboratory **A**nimal **R**esearch’s mission is to evaluate and to report on scientific, technological and ethical use of animals and related biological resources, and of non-animal alternatives in non-food settings, such as research, testing, education and production of pharmaceuticals.

IO – the Institutional **O**fficial is the individual who, as a representative of senior administration, bears ultimate responsibility for the program and is responsible for resource planning and ensuring alignment of program goals with the University’s mission.

OLAW – the **O**ffice of **L**aboratory **A**nimal **W**elfare provides guidance and interpretation of the Public Health Service Policy on Humane Care and Use of Laboratory Animals (referred to as the Policy), supports educational programs and monitors compliance with the Policy by assured institutions and Public Health Service funding components to ensure the humane care and use of animals in Public Health Service-supported research, testing and training, thereby contributing to the quality of Public Health Service-supported activities.

Performance standard – is a standard or guideline that, while describing a desired outcome, provides flexibility in achieving this outcome by granting discretion to those responsible for managing the animal care and use program, the researcher and the IACUC.

PHS - **P**ublic **H**ealth **S**ervices’ policy is to require institutions to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training and biological testing activities conducted or supported by the PHS. The PHS includes the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health and the Substance Abuse and Mental Health Services Administration.

Practice standard – is the application of professional judgment by qualified, experienced individuals to a task or process over time, an approach that has been demonstrated to benefit or enhance animal care and use.

Program – is the activities conducted by and at an institution that have a direct impact on the well-being of animals, including animal and veterinary care, policies and procedures, personnel and program management and oversight, occupational health and safety, IACUC functions and animal facility design and management.

Quorum – is a majority (more than 50%) of the voting members of the IACUC.

Reduction – involves strategies for obtaining comparable levels of information from the use of fewer animals or for maximizing the information obtained from a given number of animals (without increasing pain or distress) so that in the long run fewer animals are needed to acquire the same scientific information.

Refinement – refers to modifications of husbandry or experimental procedures to enhance animal well-being and minimize or eliminate pain and distress.

Replacement – refers to methods that avoid using animals. The term includes absolute replacements (i.e. replacing animals with inanimate systems such as computer programs) as well as relative replacements (i.e. replacing animals such as vertebrates with animals that are lower on the phylogenetic scale).

Significant deficiency - is a deficiency which, consistent with PHS Policy, and, in the judgment of the IACUC or institutional official, is or may be a threat to the health or safety of the animals.

Vivarium manager – is the individual responsible for the daily animal care and facility management for animals housed in Wick Science Building (WSB) Room 291 Aquatics Lab and the Integrated Science and Engineering Laboratory Facility (ISELF) Rooms 305-316B. These spaces represent the majority of the University's regularly used animal holding spaces.