Fort Hays State University
Institutional Animal Care and Use Committee
Procedures and Guidance
August 1, 2012
PURPOSE
This document provides guidance for the Fort Hays State University community regarding the care and use of animals.

POLICY
The use of vertebrate animals for teaching, research, and exhibition by Fort Hays State University must comply with public laws, policies, and guidelines and be reviewed and approved by the FHSU Institutional Animal Care and Use Committee.

Personnel involved in the research or the educational use of animals must receive appropriate training in humane handling and care of animals.

All animals used for research or educational purposes must be housed in appropriate institutional facilities that are approved by university administration and the IACUC. Construction of new facilities or renovation of existing facilities for the care and use of animals must meet or exceed federal guidelines, and must be approved by the university administration, university architect and the IACUC.

Federal Regulations
Animal Welfare Act (Public Law 89-544) and subsequent amendments (PL 91-579, PL 94-279, PL 99-198)

The purchase, sale, housing, care, handling, treatment and transportation of animals used in teaching, research, exhibitions, and those sold as pets are regulated by authority granted in the Animal Welfare Act (AWA) of 1966 and its amendments. The law is implemented in the Code of Federal Regulations, title 9, chapter I, subchapter A (Animal Welfare). Subchapter A serves as the USDA regulatory guide that defines the specific standards and requirements governing the humane handling, care, treatment and transportation of animals. Failure to comply with these standards may lead to civil or criminal prosecution resulting in substantial fines and/or suspension of animal research activities.

The act specifically includes dogs, cats, nonhuman primates, guinea pigs, hamsters, rabbits, all wild animal species and any other warm-blooded animal being used or intended for use in research, testing, experimentation, exhibition purposes or being sold as a pet. Although the AWA allows exemption for any housing facilities and activities involving the use of birds, domesticated rats and mice (genus *Rattus* and *Mus*, respectively) bred for use in research, horses not used for research and other domestic farm animals, including poultry used for food, the improvement of animal nutrition, breeding, management or production from registration, licensing, and inspection of housing and research facilities, as well as from protocol reviews, the FHSU IACUC, as allowed by the federal regulatory agencies, has determined that the use of any vertebrate animal for any activities involving FHSU personnel comes under IACUC oversight, and must comply with FHSU animal use policies and procedures based upon AWA Standards (Part 3). Recent amendments address such issues as exercise for dogs and care of non-human primates to ensure their psychological well-being. The composition and duties of an Institutional Animal Care and Use Committee (IACUC), adequate veterinary care and responsibilities of the attending veterinarian, training of all personnel using laboratory animals in humane methods of animal maintenance and experimentation, and record keeping are addressed.

The act is administered by the United States Department of Agriculture (USDA), specifically, the sector veterinary component of the Animal and Plant Health Inspection Service-Veterinary Services (APHIS-VS). Research facilities are subject to unannounced inspections by USDA veterinarians.

The IACUC is responsible for reviewing all protocols using animals to make certain the protocols meet criteria listed in the AWA amendments. In addition, the IACUC must conduct semiannual inspections of all animal study areas and animal facilities. The importance of this requirement is underscored by the fact that the chief executive
officer of the institution must certify that the attending veterinarian (AV) and IACUC have the authority to enter any animal area at any reasonable time.

The IACUC also is required to furnish annual reports that include, in addition to other information and assurancs, the common names and number of animals used, listed by procedures involving no pain or distress; pain or distress for which appropriate anesthetic, analgesic, or tranquilizing drugs were used; and pain or distress for which the use of appropriate drugs would have adversely affected the procedures, results or interpretation of the research. The report must certify anesthetic, analgesic and tranquilizing drugs were used appropriately during research and ensure the principal investigator (PI) considered alternatives to painful procedures.

Adherence to the Specific Guidelines Established by the Biological Societies

Guidelines have been established by various wildlife and biological societies (wild and domesticated) for the use of vertebrate in research. Adherence to such guidelines is required by multiple peer-reviewed scientific journals for publication of the studies in addition to adhering to the FHSU IACUC guidelines. The guideline publications are available directly from the specific publishing society. See Appendix A)

COMPOSITION AND RESPONSIBILITIES OF THE IACUC

The PHS Policy and the amendments to the Animal Welfare Act require the establishment of an Animal Care and Use Committee to ensure the care and use of animals are appropriate and humane.

Institutional Official—establishes the IACUC, supports IACUC authority and decisions, provides sufficient resources, provides educational opportunities, ensures investigators fulfill responsibilities, ensures institution-wide communication. The Institutional Official is the individual authorized on behalf of the University to assure all programmatic and regulatory requirements are met. The Institutional Official is appointed in writing by the university President

IACUC—oversees and evaluates the entire animal care and use program, and ensures compliance with federal, state and university regulations. Clearly articulates policies and procedures, assures effective training programs that are realistic, implements regulations using scientifically sound, performance based standards, facilitates research and teaching while ensuring humane animal care and use. Assures the public of quality care. Comprised of a Chair and at least two additional members. At least one shall be a DVM, and one that is not affiliated in any way with the facility other than as a member of the Committee to provide representation for the general community. If there are more than three members, not more than three shall be from the same administrative unit. FHSU IACUC members will include representatives from Biology, Chemistry, Agriculture, Sternberg Museum, Psychology, the Veterinarian, and community representative. The FHSU IACUC Administrator is an ex-officio member.

The FHSU IACUC was organized in 2012. The IACUC serves as adviser to the university administration in matters dealing with animal care and use. It also ensures university compliance with all applicable federal, state and institutional policies, laws and regulations. Responsibilities include but are not limited to:

- Develop procedures and guidelines based on Federal, State, and University policies.
- Advises the Institutional Official regarding all aspects of the FHSU Animal Care and Use Program.
- The IACUC acts as liaison between the campus and various animal care regulatory and oversight authorities.
- Monitors the use of animals in teaching, research and exhibition at FHSU animal facilities or other animal facilities utilized by university faculty and staff (i.e., contract facilities operated by another agency but utilized by FHSU personnel), and animal use by faculty from other institutions when the animals are owned by or housed in FHSU facilities, or funding is provided by FHSU.
- Reviews and inspects, at least once every six months, the University’s program for the humane care and use of animals and the status of the institution’s animal facilities, including museums and laboratories. A summary report of these evaluations will be submitted to the IO in accordance with the AWA and the PHS Animal Welfare Policy.
• Evaluates requests for use of all vertebrate animals owned by the university or used by faculty, staff, or students in research, teaching, or testing. The IACUC reviews and approves, requiring modifications (to secure approval), or withholding approval of protocols for use of animals in teaching and research. Criteria for approval shall be determined by the most current federal laws and policies. The IACUC will provide prompt review of Applications and maintain communications with the investigator.
• Reviews concerns involving the care and use of animals or reported violations of the AWA and, if warranted, investigate these concerns.
• The IACUC is authorized to suspend an activity in accordance with the AWA only after review at a convened meeting and with the suspension vote of a majority of the quorum present. The Investigator is notified by the IACUC following the suspension vote. If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reason for the suspension, take appropriate corrective action, and report that action with a full explanation to the Animal Health Inspection Service (APHIS) and any Federal agency funding the suspended activity.
• The committee will maintain communication with other university committees that have related responsibilities (such as security, occupational health and safety, physical plant, etc.).
• Prepares the annual USDA report for the university and for the signature of the IO.
• In the event an animal is discovered to be in significant pain due to injury or other cause, and after a reasonable effort to notify the person responsible for the animal has failed, or those responsible fail to take immediate action, the committee chair, AV or his/her designated representative has the authority to immediately direct alternative care, administer analgesics or euthanize the animal as appropriate.
• Assists in establishing training procedures for scientists, students, research technicians, animal technicians and other personnel involved with animal use, care and treatment.
• The IACUC is responsible for maintaining a list of animal housing sites at this university. Maintenance of such a list is a legal requirement.
• Each approved animal housing facility is subject to oversight by the IACUC and the USDA.

The following criteria for establishing the FHSU IACUC were developed from the Animal Welfare Act (AWA) and PHS policy. The members of the committee are appointed by the IO and include:

• Four practicing scientists experienced in animal research.
• One member whose primary concerns are in a non-scientific area.
• One member not affiliated with the university and not a member of the immediate family of a person who is officially affiliated with the university.
• A practicing veterinarian who has training or experience in animal science and medicine or in the use of the species in question.
• Appointments may include, but are not limited to: representatives of FHSU departments and units whose faculty members use animals in research, teaching, and exhibition.

The IACUC Administrator is an ex-officio non-voting member and acts as a consultant to the committee.

Consultants may be used by the IACUC in areas of special needs that are not covered by members of the committee.

The Attending Veterinarian has delegated authority for activities involving animals on the FHSU campus. The Attending Veterinarian oversees the health care of animals used by FHSU. The Attending Veterinarian has appropriate authority to ensure the provision of adequate veterinary care and oversee the adequacy of other aspects of animal care and use. The Animal Welfare Act regulations hold the Attending Veterinarian directly responsible for the oversight of animal disease control and prevention, euthanasia, the appropriate use of pain-relieving drugs, and other aspects of veterinary care. The Attending Veterinarian must be currently in practice and is a full voting member of the IACUC.

The chair of the committee will be appointed by the IO and will serve as a non-voting member except in instances of a tie vote.
The Principal Investigator (PI) is the individual responsible for research, teaching project(s) or exhibition(s) using vertebrate animals. PIs are responsible for preparing and submitting an Animal Care and Use Protocol prior to any teaching or research activity, and for adherence to the approved protocol. PIs are responsible for knowing the requirements of the agencies from which they seek funding, and submitting approved Animal Care and Use Protocols to their funding agencies as required.

**Authority of the IACUC**

The IACUC has the authority to withdraw approval to use animals from any project that is not being conducted in accordance with the approved protocol or is not in compliance with the guidelines. Any withdrawal of approval will be based on a thorough investigation by the IACUC that includes an opportunity for the principal investigator to provide information, explanation, and if appropriate, the course of action to be taken to alleviate the cause for withdrawal of approval.

Resolution of the cause(s) for withdrawal of approval will result in reinstatement of approval and continuation of the work.

If an investigator continues with a project for which he/she has been notified that approval has been withdrawn, the investigator will be subject to withdrawal of approval of all projects. The IACUC must report major deficiencies in projects to the funding agency as soon as they are identified. If non-compliance continues, a recommendation by the IACUC to the funding agency to terminate funding would be in order.

The authority of the committee is delegated by the FHSU Dean of Graduate Studies and Research through the IO, for the purpose of performing the duties and functions set forth in the following documents:

- Public Health Service Policy on Humane Care and Use of Laboratory Animals
- The Animal Welfare Act (89-544) and amendments
- The Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching
- Health Research Extension Act of 1985 and amendments
- FHSU Policies & Procedures Manual for the Use of Animals (this document)

**POLICY ENFORCEMENT AND COMPLIANCE**

**IACUC Programmatic Evaluation**

The IACUC reviews the animal facilities and programs for animal care using as its criteria The Guide and standards set forth in the Ag Guide. Reports are made to the IO and facility administrators who are, in turn, responsible for correcting deficiencies noted by the reviewers. If assistance from department heads, deans or other administrative officials is needed, facility administrators should ordinarily assume responsibility for seeking such assistance. The IACUC Administrator, IACUC and AV will offer whatever assistance they can. They will initiate informal and formal actions to correct deficiencies whenever intervention is necessary to assure humane treatment of animals and to protect the interests of the institution.

**USDA Inspection**

Unannounced inspections are conducted by the USDA. Generally, one annual visit per site is accomplished. Criteria used by the USDA are found in Title 7, Chapter 54, Sections 2131-2159 of the Federal Code of Regulations. These are published in the USDA publication "Animal Welfare Act and Animal Welfare Regulations”,

USDA inspectors are not responsible for inspecting agricultural animals (unless they are used for biomedical research), rodents or domestic birds.
IACUC Inspection

All designated animal facilities are subject to bi-annual inspection by the IACUC. The dates and times for the in-house inspections are scheduled with animal facilities managers and unit administrators, but unannounced visits may occur as needed. The inspection schedule is approved by the IACUC and distributed to all PIs, animal facilities managers and department heads or chairs.

All FHSU, USDA and other inspectors shall abide by the security measures required by the research facility to reduce the spread of disease, including the use of clean clothing or showering between facilities where appropriate. Inspection personnel will take special care not to interfere with research being performed, unless willful disregard of animal welfare is found.

The IACUC will inspect all animal facilities, including study areas, satellite facilities and inspect the animal facilities and activity areas at least once every 6 months.

Study area: Any building, room, area, enclosure, or other containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 12 hours.

Animal facility: Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments.

In addition, PHS requires using the Guide for the Care and Use of Laboratory Animals (aka The Guide) as a basis for evaluation while the AWA requires using ‘title 9, chapter I, subchapter A-Animal Welfare’ as a basis for evaluation. Furthermore, throughout the PHS POLICY are reminders that ‘Assured institutions ... comply with the regulations ... issued by ... USDA...’

1. The PHS definition indicates that all vehicles used to transport animals be inspected as well.
2. By every six months, OLAW and APHIS mean it has to happen within six months of the previous.
3. PHS POLICY that the IACUC ‘may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities’ (p. 7) allows for the use of subcommittees to conduct inspections.
4. 9CFR§2.31(c)(3) outlines the use of subcommittees to meet USDA requirements. The make-up of subcommittees is at the discretion of the IACUC but should include at least 2 members.

INSPECTIONS AT FHSU:
1. The focus is amicable inspections to promote voluntary attempts at compliance.
2. IACUC inspections are conducted in September and March (on campus and Sternberg) and July and January (Wetlands Center).
3. Inspections are conducted by at least 2 IACUC members.
   a. In the protocols, PIs must identify the facilities and location in which procedures will be conducted. These facilities and locations will be made available for inspection.
   b. If the facility has had animals in it at any time in the previous six months, or is projected to have animals within the following six months, it is included in the inspection.
4. Although the inspections are announced with the schedule published in advance, the IACUC reserves the right to hold unannounced inspections.
5. A departmental representative accompanies the IACUC on the inspections and is to have made arrangements for the PI or senior tech to be available during the inspection. This affords an opportunity for exchange of information between the research teams and the Committee in which the Committee learns more about the research and the research teams learn more about the IACUC and the rules and regulations. There also can be a discussion of future research plans, occupational health issues, and animal welfare concerns.
6. The Institution’s custodial staff assists with enforcement of policy by notifying the IACUC of any perceived ‘irregularities’, like animals housed in filing cabinets or discarded in trash cans. The IACUC will provide appropriate guidance to train the custodial staff.
INSPECTION RECORD KEEPING AND REPORTING:
1. The checklist used during inspections serves as the required written report.
2. For the semi-annual inspection report, a cover page listing any findings is attached to all the checklists for the preceding six-month period.
3. The reports must contain a description of the nature and extent of the research facility's adherence to the USDA regulations, PHS Policy, and or the Guide.
4. The reports must identify specifically any departures from the USDA, PHS, and Guide requirements and must state the reasons for each departure. (A departure from standards is a deviation for some legitimate, generally scientific, reason whereas a deficiency is a deviation w/o a legitimate, IACUC-approved purpose.)
5. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is a one which, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals (9 CFR §2.31(c)(3)and IV.B.3).
6. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency.
   a. The regulations are vague as to who has the responsibility to assure that deficiencies are corrected, so have a plan.
   b. Corrective action should be monitored in writing and with follow-up inspections so you have a 'paper trail'.
7. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported “promptly” to OLAW (if needed) and “in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity” (9 CFR §2.31(c)(3) and IV.F.3).
8. USDA requires the inspection report 'be reviewed and signed by a majority of the IACUC members and must include any minority views' (9 CFR §2.31(c)(3)). PHS does not have a similar requirement for signatures.
9. PHS requires this report be submitted to the Institutional Official.
10. Both USDA (9 CFR §2.35(a-f)) and PHS (IV.E.1-2) require the reports be kept on file for 3 years.
11. The report does not have to be submitted to either USDA or Public Health Service. For USDA it must be 'made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request'; PHS requires the date of the inspections be included in the annual report to OLAW.

Individual Responsibilities

Department Chairs/Heads and Facility Administrators

Administrators must be aware of animal care and use requirements and assure that policies and procedures (herein) are implemented and the standards are maintained. They must assure safeguards and safe procedures are maintained in the work place for all employees and that occupational health and personal hygiene standards are adhered to by faculty, staff and student employees.

They must assure that animal research and other use is appropriately reviewed and approved, before initiating work. They should remind new faculty that an IACUC Application must be completed as part of grant proposals. And before research projects or academic use of animals begins the application must be approved by the IACUC.

They must assure that support staff clearly understand and follow the procedures and expectations for animal care, safety and well being, and discuss any questions or concerns with the principal investigator.

Department administrators may call upon or alert the IACUC or seek their guidance in addressing unique needs. Support from the department chair/head can make the duties of the IACUC much easier.

It is the responsibility of each department to hire qualified personnel as animal caretakers.

Supervisors of new employees are required to notify the IACUC of the employees’ names and starting date. Continuing education is required for all personnel working with animals within FHSU animal research facilities. It
is the responsibility of the IACUC to establish training and continuing education programs. When training is provided by the PI and documented, this will help meet the training requirements.

The supervisors of new employees, including part-time student employees, undergraduate students, graduate students, technicians or others working with animals, are required to training sessions appropriate to their assignment.

**Investigators**

The integrity of the investigator is the most valued part of responsible animal use. All investigators using animals in teaching, research or education are responsible to ensure that their staff (both professional and technical) and any students and student employees under their supervision know how to handle and properly care for the species being used. Staff must also know how to perform the techniques being used. The IACUC Administrator should be consulted if there are questions. FHSU provides CITI training and the IACUC will assist with specialized training as requested.

The research investigator or instructor is responsible to design experiments or activities involving animals to assure compliance with federal, state and university regulations and policies. Investigators should try, whenever possible, to reduce the number of animals used, refine techniques to minimize pain or suffering, and replace animals with alternative or adjunctive methods if available. Unnecessary replication of studies may be avoided by using proper literature reviews and the literature reviews should be documented in the application. Investigators should assure that animal unit managers, care staff and student employees have access to the approved document.

In procedures involving unavoidable pain or distress, the investigator must justify the procedure in accordance with current federal regulations and the policies of the IACUC.

Projects with procedures that may cause more than momentary or slight pain or distress to the animals must be discussed with the AV or his designee during the planning stages.

**All Personnel Who Work with Animals**

Training of all full- or part-time undergraduate students, animal care staff, technicians, graduate students and faculty to assure and maintain proficiency and compliance in working with animals is a requirement of the AWA. In order to comply with these requirements, each new employee fitting into one of the above categories is required to complete the appropriate CITI training. This training focuses on animal care and regulations for using animals.

A record will be kept so the IACUC can verify that appropriate training has been provided before approval will be granted for requests where those students, technicians or graduate students are listed as part of the project. When training is provided by the principal investigator (PI) or other qualified personnel, a letter to the IACUC Administrator indicating who was trained and what subjects were covered would help the IACUC confirm that adequate training has taken place.

If a program or investigator continually has deficiencies in compliance with the guidelines as set forth in this document, the IACUC will make requests for associated personnel to have additional training and may discontinue the project if deficiencies are not removed or corrected.

It is essential for those who use and care for animals to maintain a high standard of personal cleanliness and hygiene to reduce the chance of transmission of pathogens, parasites or disease. Eating, drinking, and applying cosmetics may present a risk. Smoking is not permitted in campus facilities. Facilities and supplies for meeting personal hygiene requirements should be made available in all animal housing areas.

Employees working with animals, livestock, poultry or wildlife should wear appropriate clothing for the specific activities. Guidelines for personnel clothing may be unique for some animal units and activities.
Personnel must not eat, drink, smoke or apply cosmetics in animal rooms. In compliance with Drug Enforcement Agency laws: "Investigators must ensure that all anesthetic and tranquilizing drugs which are listed in schedules I-V of the Controlled Substance Act are kept locked within a cabinet. Usage of certain scheduled drugs must always be written in a log book by the investigator." (Controlled Substance Act of 1970; Public Law 91-513; Revised Jan 1979).

**Submission of FHSU Application to Use Animals Form**

The application must be submitted to the IACUC for review in any teaching, research or exhibition proposal involving the use of vertebrate animals.

The application should be filled out completely and all questions answered to avoid unnecessary delays in processing. Additionally, if funded by extramural support, the protocol must match the grant proposal with which it is submitted.

The application forms and other required documents are available electronically at www.fhsu.edu/academic/gradschl/ossp/iacuc/

Once forms are completed, they should be routed to the OSSP for appropriate review and approval from the IACUC.

All projects involving the use of animals must be reviewed and approved by the IACUC before work on the project begins.

**APPLICATION PROCEDURE**

All instructional, research and exhibition proposals utilizing living vertebrate animals must be submitted for review and approval by the IACUC. Also included are animals collected for a live or preserved collection, animal tissues and organs collected on campus for research, teaching or exhibition. Exceptions include the Rodeo Club and the use of privately owned animals used solely for instruction or exhibition. Work utilizing vertebrate animals at FHSU may not be initiated until notification of IACUC approval has been received. Student organizations that sponsor activities that involve the use and care of animals must have their faculty sponsor submit the appropriate form and receive approval from the IACUC prior to initiating those activities.

- An Animal Care and Use Protocol must be completed and approved before any activity involving vertebrate animals is initiated. Any changes to this protocol must be approved by the Institutional Animal Care and Use Committee (IACUC) before implementation.
- All personnel with the exception of undergraduate employees and research assistants working with vertebrate animals must be listed on the protocol roster and complete CITI training prior to the initiation of the activity, unless there is an exception made by the IACUC.
- Undergraduate students exposed to any activity involving vertebrate animals must be informed and trained by their instructor or supervisor about the potential risks associated with, and proper handling of animals.
- All research activities using vertebrate animals are reviewed every three years unless the proposed study has been completed before the expiration and the PI informs the IACUC of non-renewal. Each investigator or instructor with an approved Animal Care and Use Protocol is required to send an annual update to the IACUC indicating whether the project is still active and whether there have been any changes in the personnel or experimental procedures with respect to the use of animals. Three year continuation renewals are reviewed and approved by the IACUC before the expiration of the protocol.
- All teaching activities using vertebrate animals are reviewed annually. Each instructor with an approved Animal Care and Use Protocol is required to send an annual update to the IACUC indicating whether the class is offered and whether there have been any changes in the personnel or procedures with respect to the animals. Annual renewals are reviewed and approved by the IACUC before the expiration of the protocol.
IACUC approved activities may be subject to further review and approval by university officials; however, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

The IACUC is required to follow the USDA Animal Welfare Act, the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching*, and PHS Policy to oversee the FHSU Animal Care and Use.

Housing, Care, and Handling of Animals

The housing and care of animals at FHSU must conform to the Animal Welfare Act and the *Guide for the Care and Use of Agricultural Animals in Agricultural Teaching and Research*, as appropriate for their research, teaching and exhibition activities.

Animals shall be housed only in facilities inspected and approved by the IACUC. Animals removed to other areas (e.g., laboratories) for research or teaching purposes must be returned to an approved holding facility at the end of the working day. Animals cannot be housed outside of approved facilities for longer than 12 hours unless such housing is specifically justified and approved by the IACUC.

No animal or animal carcass used for teaching and research shall be removed from or brought onto FHSU property except in accordance with established campus procedures and prior approval by the IACUC.

Animal carcasses shall be disposed of in a manner consistent with current FHSU policies and Kansas Department of Health and Environment requirements. Disposal of pathogenic waste must be conducted in accordance with the Ellis County Public Health Department requirements.

**Personnel Requirements**

There are several requirements for all personnel listed on the protocol. The person submitting the proposal must be a FHSU employee who is a faculty, museum director, or instructor. The individual submitting the proposal is responsible for providing or ensuring that the students and staff that are involved in the activity have received appropriate training. The individual submitting the proposal is also responsible for the supervision of the students and/or staff involved in the activity.

**Training Requirements:**

Completion of the appropriate CITI training is required prior to submission of Form A by faculty. Graduate students must complete the appropriate CITI training prior to initiation of activity. It is the responsibility of the faculty member to make sure that any undergraduates involved in the activity receive appropriate training and supervision.

All staff at Sternberg Museum, the Wetlands Center and Farm Supervisors that are involved in the use and care of animals are required to complete the appropriate CITI training prior to initiation of activities.

**Protocol Submission**

Faculty, investigators and museum directors submit new protocols using the appropriate form.

**Form A:** This form is to be used primarily for research, museum collections. Instructional activities that contribute to these purposes are also covered by this application. For example, use this form if students enrolled in a class are gathering specimens (actual or digital) for a museum collection. Another example would be for "hands on" activities engaged in by students such as banding, trapping, seining, and specimen preparation. There may be other covered activities.

**Form B:** This form is used for non-invasive, non-painful teaching, observations or demonstrations.

Form A should be completed and submitted electronically using the "Submit" button on the form. Form B should be printed and sent directly to the OSSP.
If the proposed research is for a graduate student thesis, the student shall be expected to complete the form on behalf of the faculty mentor who shall serve as the PI. It is strongly recommended that the faculty mentor ensure that the protocol is ready for review.

The individual submitting the protocol for review must verify that the information provided is accurate and complete, and acknowledge his or her responsibility for the ethical performance of the research, instruction or exhibition, the welfare of the animals involved, and strict adherence to any conditions required by the IACUC.

Proposed protocols are required to provide:

- Species and approximate numbers to be used
- Rationale for using animals and appropriateness of species and numbers
- Complete description of proposed use
- Description of procedures to assure that discomfort and pain will be minimized
- Description of methods of euthanasia
- Use of agents to relieve pain/distress
- Medical care
- Personnel experience, qualifications and training
- Alternatives
- Euthanasia and disposition – care of long lived species after study completion
- Roles and responsibilities of personnel involved, not just training and experience

**Deadlines**

Proposals are accepting on a rolling basis. Proposals are due in the OSSP no later than one month prior to the convened IACUC meeting. See [http://www.fhsu.edu/academic/gradschl/osspiacuc/](http://www.fhsu.edu/academic/gradschl/osspiacuc/) for meeting and deadline dates.

**Review Process:**

An administrative review is conducted when the proposal is submitted to the OSSP. The proposal will be assigned a number, and logged into the database.

The proposal is reviewed to determine

- if it has been completed,
- if all necessary documents (such as permits) have been included,
- if the required training has been completed.
- If the activity is receiving extramural or intramural funding, review the activities described in the proposal and the grant for consistency.

The OSSP administrator will communicate questions or concerns to the individual submitting the proposal. Once the submission has been finalized, the OSSP administrator will forward the submission to the IACUC Chair for assignment, and to the Attending Veterinarian (AV) for review.

**Attending Veterinarian Review:**

The Veterinarian considers the following during review:

- Description of the procedures – do they meet veterinarian standards?
- Alleviation of pain/distress- are measures adequate? Are drugs appropriate?
- Personnel training for the procedures
- Can facilities accommodate the study?
- Adequate response to the 3 Rs?
• Appropriate pain category classification?

Prior to the meeting, the OSSP Administrator, IACUC Chair and the Attending Veterinarian (AV) will consult regarding prioritizing protocols, based on level of pain/distress, species being used, types of procedures, initial protocol, progress report, etc.

The IACUC may review the protocol or amendment by Designated Member Review (DMR), by Full Committee Review (FCR) or by Facilitated Review (FR). Any IACUC member may request that a protocol be reviewed by FCR. The AV reviews all protocols.

Full Committee Review

All initial submissions will be reviewed by the Full Committee. All members have access to the protocol prior to the meeting and have the ability to ask questions. Committee members review the protocols to ensure that they are consistent with the guidelines, regulations and FHSU policies regarding animal use and care. The reviewers are responsible for reviewing the entire protocol. They prepare written critiques of each protocol assigned to them and their individual recommendations regarding approval. Questions from the IACUC members will be compiled by the OSSP administrator and forwarded to the PI for response. The protocol will be discussed by a quorum of IACUC members at a convened meeting. All IACUC members are expected to review each protocol and make verbal comments during the meeting. During the meeting, any differences between reviewers are resolved and comments by members of the committee are documented. The entire committee votes on the recommendation for approval. Members who are associated with the protocol or have a conflict of interest abstain from voting.

Possible recommendations for initial reviews:

• Recommended for approval. The protocol complies with all requirements and regulations (USDA, PHS). However, the PI must consider and incorporate any suggestions from the IACUC, and must respond to any administrative questions. The PI does not need to make another submission, and the suggestions will be included in the approval letter.

• Modifications are required to secure approval. The protocol complies with all requirements and regulations (USDA, PHS) but minor questions and/or clarifications must be resolved to secure approval. For example, the IACUC may approve the protocol with a condition. The PI must submit an addendum addressing the questions and/or concerns raised by the IACUC in order to secure approval.

• Tabled, request for major revisions or for additional information. The protocol either does not comply with all the above requirements or there are serious questions that must be resolved to secure approval. Will require Full Committee Review.

• Approval Withheld. The protocol either does not comply with all the requirements or the PI will not agree to comply with the IACUC’s requirements.

Facilitated review

Protocol changes that are considered MINOR can be reviewed by the facilitator. Changes that include changes to the title of a protocol or a funding source, adding a new strain or genetic background of animal, an addition of animals to the protocol that does not exceed 10% of the originally approved number of animals for that species, and the addition or removal of personnel to a protocol, are considered as minor. Any other changes are NOT MINOR, and must be reviewed by a Designated Member or by the Full Committee.

Facilitated Reviews are conducted by the IACUC Chair and AV. Either may determine that the protocol needs to be reviewed by the DMR or FCR.

• Recommended for approval. The protocol complies with all requirements and regulations (USDA, PHS). However, the PI must consider and incorporate any suggestions from the IACUC, and must respond to any administrative questions. The PI does not need to make another submission, and the suggestions will be included in the approval letter.
- Minor modifications are required to secure approval. The protocol complies with all requirements and regulations (USDA, PHS) but minor questions and/or clarifications must be resolved to secure approval. For example, the IACUC may approve the protocol with a condition. The PI must submit an addendum addressing the questions and/or concerns raised by the IACUC in order to secure approval.
- The protocol will need DMR or FCR.

Designated Member Review

Designated member review (DMR) will be used for continuation requests or significant modification of an approved protocol unless the designated reviewer requires that the protocol come back for FCR. Any changes to a protocol that present animal welfare issues not addressed in the original protocol are considered to be significant.

Amendments that do not fall into the categories listed as "minor" must be submitted by the PI to the IACUC for review. Significant modifications include a change in animal care facility, housing unit or field site, a change in administration of experiment/treatment as it relates to the timing, dose, route of administration and/or specific chemical composition, and anything not listed as minor. The e-mail or cover letter should reference by number and/or title of the protocol to be amended, and provide a summary and justification for all requested changes.

Submissions must include sufficient information for the IACUC to evaluate changes using the same criteria as in the initial review. The principal investigator must clearly explain why the modification is being requested and how it relates to the original specific aims of the previously approved protocol. Attached to the e-mail or cover letter must be a revision of the previously submitted and approved IACUC form. The submitted protocol should incorporate all minor amendments approved since the initial protocol approval (or since the last significant amendment approval). If you cannot find your protocol, please contact the OSSP for a copy.

The complete details of the proposed amendment must be incorporated into the revised IACUC form. Revised text should be clearly indicated in bold and underlined fonts. For instance, if the PI requires an additional field study or species, or if an increase in animal numbers is requested beyond the 10 % of original estimate, the PI must provide the reasons for the additional field study, or for the need of additional animals and justification for the number requested.

Continuation requests

USDA Animal Welfare Regulations require that the IACUC conduct continuing reviews of activities involving live animals not less often than once per year, but do not require that this annual review be conducted by the full IACUC at a convened meeting. The Public Health Service Policy requires that the IACUC conduct a complete review of all previously approved ongoing activities at least once every three years.

FHSU IACUC complies by:

- allowing two annual progress reports that are reviewed by DMR or FR, and
- a complete resubmission of the full protocol for full committee review every three years.

An annual progress report must be submitted and approved by the IACUC before the first and second annual expiration date of the original IACUC-approved protocol. The annual progress report provides the researcher with an opportunity to update animal usage and report adverse events as well as refinements to the procedures proposed in the approved protocol. The PI listed on the protocol will receive an email approximately 90 days prior to the anniversary date, with a follow up reminder 30 days before the protocol expires. The 30-day renewal reminder letter is copied to the Investigator’s Department Chair.

An Annual Progress Report form must be received by the OSSP at least two weeks prior to the expiration date, to allow sufficient time for administrative review and approval by the IACUC Chair.
The IACUC Administrator reviews all applications received for their completeness and accuracy and will return the renewal application to the Investigator if the application is incomplete or inaccurate. Any IACUC member, including the unaffiliated and nonscientific representatives, with interest in an annual renewal may request a copy and submit a review of the annual renewal and/or call the annual renewal to full committee review. Following the administrative review, the report will be reviewed by the IACUC Chair. If no problems are identified in the report, annual renewal is approved by the IACUC Chair. No annual renewal application is approved unless all training requirements have been met. Investigators who do not submit renewal applications will have their IACUC approval terminated.

The approval to use animals in research, testing, and teaching expires on the date of protocol expiration (one year from previous approval date) if a progress report or continuation application have not been approved. If no response is received by the expiration deadline, the IACUC will terminate the approval of the protocol in a letter to the Investigator, with copies going to the Investigator’s Department Chair and the Institutional Official. If a protocol lapses in approval, the study is suspended and the animals are off limits to investigators and research personnel until the Full Committee has approved the new application. No experimental use or observation of animals may take place during a protocol lapse period – failure to act in accordance with this restriction will be handled as regulatory noncompliance. Arrangements must be made for the care of the animals by the respective department or university unit.

Three Year Continuing Renewal

All animal use protocols must be submitted for full committee review at a convened meeting of the IACUC every three years. This review is sometimes called a de novo review because the protocol receives the same scrutiny by the committee as it would if it were a brand-new submission. PIs should not assume that their three-year renewal protocol will automatically receive approval; many factors may have changed since the last full committee review, including federal animal welfare regulations, societal expectations, and the composition of the committee. As is the case with annual progress reports, the protocol expires on its expiration date if a three-year renewal application has not been reviewed and approved by the IACUC. During the lapse in approval, animals are moved to an approved holding protocol and are off limits to investigators and research personnel and may not be used for experiments or observation. There are no exceptions and no extensions of approval granted by the IACUC.

The PI will receive a three-year reminder memo via email approximately 90 days prior to the anniversary date, with a follow up reminder 60 days before the protocol expires.

IMPORTANT NOTE: Do not use versions of the IACUC application forms that may be stored on your computer from an earlier submission; the application forms should be downloaded from the web each time they are used. The forms may be updated and revised, and outdated forms will not be accepted for IACUC review.

Submission of the three-year renewal:

1. The PI must download and complete the current version of the IACUC Application form from the web.
2. PIs should determine the best meeting date for review of their protocol. The IACUC recommends that three year renewal protocols be submitted for review 90 days in advance of protocol expiration, to avoid delays in approval that could cause the protocol to expire.

Reviews of significant amendments and continuations by the IACUC may be assigned for designated member review. The PI may request up to two IACUC members as the designated reviewer. The IACUC chair assigns the designated reviewer.

All IACUC members receive the protocol for review. Committee members will have two weeks to request that the protocol be removed from DMR and placed on the next agenda for full committee review.
After the two weeks, if there are no objections to the DMR request, the designated reviewer can:

- Approve the protocol/amendment as presented.
- Request modifications.
- Request a full committee review.
- Disapproval

1. It is strongly recommended that three year renewal protocols be submitted for review 90 days in advance of protocol expiration, depending on the IACUC meeting schedule. This will allow for sufficient time for administrative review, assignment for DMR or for FCR when needed and to avoid delays that could result in expiration of the protocol.
2. The approval to use animals in research, testing, and teaching expires on the date of protocol expiration (one year from previous approval date) if a progress report or continuation application have not been approved.
3. If a protocol lapses in approval, the study is suspended and the animals are off limits to investigators and research personnel until the Full Committee has approved the new application.
4. No experimental use or observation of animals may take place during a protocol lapse period – failure to act in accordance with this restriction will be handled as regulatory noncompliance.
5. Arrangements must be made for the care of the animals by the respective department or university unit.

**Disapproval of a protocol**

If an Investigator refuses to modify a proposal in accordance with the full IACUC’s directions, or fails to supply information showing that their department has appropriate facilities and staff for the proposed research, the IACUC may decide not to approve the protocol. The specific reasons for disapproval will be provided to the investigator in an email.

Appeals of a decision not to approve an application may be submitted to the IACUC Chair. Appeals must include additional evidence that was not previously made available or the solicitation of experts able to assist the IACUC in their deliberations. Disapproved proposals cannot be administratively approved by a higher authority. However, an IACUC approved protocol can be administratively disapproved due to financial, facility-related or other considerations.

**Termination of a protocol**

The IACUC may terminate an approved protocol due to the following reasons:

- Non-compliance issues
- Failure to renew annually
- Failure to complete required training

For non-compliance issues, particularly those that involve animal welfare concerns, protocols may be terminated immediately. For failure to renew annually and failure to complete required training, the Investigator is given a 30 day notice prior to termination.

The PI will be notified of protocol termination by email message. The Department Chair or Unit Administrator will be notified of all IACUC terminated protocols and will decide the disposition of study animals.

Investigators with protocols that have been terminated due to failure to annually renew must submit an application immediately and address any training or other issues right away. The IACUC will not approve annual renewal applications thirty days after termination. If an annual renewal application is not approved in this time frame, a new protocol application must be submitted, reviewed and approved before research may continue.

**Withdrawal**
The IACUC may withdraw any pending protocol from the review process if the PI does not respond in a timely fashion during the review process. This occurs when questions are sent to the PI and the PI takes longer than two months to respond. The IACUC will send notice to the PI that the protocol will be withdrawn from the review process if a response is not forthcoming. The IACUC may also withdraw applications for review if any training requirements are not satisfied in a timely manner.

Notifications

E-mail notification of the Committee’s decision is sent to the PI following the DMR or Full Committee decision. The finalized approved and signed copy of the protocol or amendment is maintained on file in the OSSP and a copy of the approved protocol and signed cover letter will be provided to the PI.

Protocol Modifications

Both the AWA and PHS Policy require that the IACUC review and approve, prior to initiation, proposed modifications to ongoing activities using animals. Modifications are submitted to the IACUC using a Modification Request Form. All requests are reviewed using the same process and have the same requirements. The following modifications cannot be requested using this process:

- Changing the species used
- Adding procedures that do not logically relate to the specific aims of the original protocol
- An unrelated change in the scientific aims of the original protocol application
- Switching from non-survival to survival surgery
- Switching from single to multiple survival surgeries.

A new protocol application must be submitted to incorporate any of the above changes, because the IACUC is required to review new issues arising related to animal welfare. Any changes to an IACUC protocol that present animal welfare issues not addressed in the original protocol will require the submission of a new protocol. The new protocol submission is required to address how all animal welfare issues will be mediated. Two types of modifications are recognized. An Administrative Modification is an addition or deletion of personnel or an Investigator, protocol title change or additional protocol titles, a change in the funding source, a change in the animal source or vendor, a request for animal housing or use outside the Institution that meets established IACUC requirements or a request for additional animal strains that do not require additional husbandry or housing considerations beyond those in the approved protocol.

Administrative modification requests are reviewed by IACUC Office personnel, and if appropriate changes have been made to the protocol and records, they grant approval usually within two to three business days. Requests for additional personnel require that the new personnel satisfy all IACUC and EH&S mandated training and safety requirements prior to approval.

Other acceptable modifications to an IACUC-approved protocol include: changes in anesthetic or the analgesic agents, changes in euthanasia method(s), requests for additional animals, changes in nonsurgical procedures involving animals, changes in the animal strain, any changes that will affect the previously approved USDA Pain/Distress Category, requests to use additional test agent(s), and other changes that logically relate to the specific aims of the original protocol application.

The PI must clearly explain why the modification is being requested and how it relates to the original specific aims of the previously approved protocol. Modifications are reviewed using nearly the same process as new protocols. The modification request is assigned to at least three designated reviewers: 1 scientific member, 1 veterinarian, and an administrative reviewer. Questions and answers circulate between the reviewers and PI. After all issues have been resolved, and all reviewers have issued an approval, the request is approved and, after review by the IACUC Chair, an approval letter is issued.
Certain modifications are administratively flagged for full committee review: requests for more than 10% of the originally-approved number of animals justified for the study/experiments, modifications involving death as an endpoint, and requests for new >12 hour housing sites outside of designated space all must be approved by the full IACUC.

Policy on Reporting Animal Concerns
In accordance with the Animal Welfare Act, (9 CFR Ch.1), Part 2 - Subpart C 2.32. Training and Instruction of personnel must include:

(4) Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee members, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations or standards under the Act.

Methods for Reporting Animal Care and Use Compliance Violations at FHSU
1. Often, the preferred first course of action is to discuss the issue and resolve it on site with the individuals present.
2. If this is not possible or is not successful, a report (anonymous or not) may be submitted to:
   _ IACUC phone 785-628-4349
   _ Email to iacuc@fhsu.edu
   _ Mail to IACUC/Office of Scholarship and Sponsored Projects
   _ The following individuals who are responsible for animal care and use at FHSU:
     IACUC Administrator 785-628-4349
     Chair, Institutional Animal Care and Use Committee 785-628-5835
     Institutional Official 785-628-4231

All reports are treated seriously and are investigated. Corrective action is taken as appropriate. No facility employee, Committee members, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations or deviations from standards.

Federal Requirements Regarding the Reporting of Animal Care and Use Concerns:
USDA -- ANIMAL WELFARE ACT (9 CFR Ch.1) Part 2 - Subpart C 2.31 (c) IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility shall:

(4) Review, and if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees;
2.31 (d) (6) The IACUC may suspend an activity that it previously approved if it determines that an activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee. 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;
(7) 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 APHIS and any federal agency funding that activity.

2.32 Training and Instruction of personnel must include
(4) Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee members, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations or standards under the Act.

2.33 (2) Each research facility shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use. (USDA provides the authority and responsibility to the attending veterinarian to temporarily suspend an activity involving animals.)
PUBLIC HEALTH SERVICE POLICY (implementation of Public Law 99-158)

B. Functions of the IACUC

4. Review concerns involving the care and use of animals at the Institution;

C. IACUC Review of PHS-conducted or Supported Research Projects

6. 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 institution's Assurance, or IV.C.I.a-g of this Policy. The IACUC may suspend an activity only after a 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.

7. 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

F. Reporting Requirements

3. The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to: a. any serious or continuing noncompliance with this Policy; b. any serious deviation from the provisions of the Guide; any suspension of an activity by the IACUC.

NONCOMPLIANCE POLICY

GUIDELINES FOR EVALUATING INVESTIGATOR NONCOMPLIANCE

Approved: ______________

Mandate

The PHS Policy on Humane Care and Use of Laboratory Animals (Policy) identifies three areas that require prompt reporting to OLAW (Section IV.F., paragraph 3):

(a) any serious or continuing noncompliance with the PHS Policy;
(b) any serious deviation from the provisions of the Guide for the Care and Use of Laboratory Animals; and
(c) any suspension of an activity by the IACUC.

OLAW Guidance

According to OLAW, the IACUC should apply professional judgment in determining whether a problem falls within the letter or spirit of either (a) or (b) and if it should be reported to them. OLAW has provided examples of occurrences that they have determined meet the reporting criteria: {May need to be revised based on 2/24/05 OLAW guidance.}

(a) serious or continuing noncompliance with the PHS Policy
1. failure to correct situations identified in previous semiannual evaluations as significant deficiencies
2. conducting animal-related activities without appropriate IACUC review and approval
3. failure of animal care and use personnel to adhere to IACUC - reviewed and approved institutional policies and procedures
(b) serious deviation from the provisions of the Guide
1. conditions that jeopardize the health or well-being of animals, including accidents, natural disasters and mechanical failures resulting in actual harm or death to animals
2. shortcomings in programs of veterinary care, occupational health or training, identified during semiannual program review and not corrected within the institutionally determined time frame.
(c) suspension of an activity by the IACUC
1. an IACUC intervention that results in the temporary or permanent interruption of an activity involving animals

Information Gathering and Committee Assessment

When incidents are identified in which investigators have conducted animal-related activities without appropriate IACUC review and approval or failed to adhere to IACUC - reviewed and approved institutional policies and procedures, the IACUC Administrator or veterinarian should provide the committee members with factual information on the incident. This should include the type of incident (e.g., unapproved procedure, housing violations, lack of skill/training, neglect, wasted animals) and details of the specific events (e.g., species, procedures performed, adverse effects, individuals involved).

Committee members should then consider the following questions in determining whether to report the incident
to OLAW. {May need to be revised based on 2/24/05 OLAW guidance.}
1. In what humane use category would the procedures have been?
2. What were the adverse effects on the animals being used?
3. Might the adverse effects have been prevented if the procedures had been reviewed by the IACUC and the veterinary staff?
4. Was medical intervention by the veterinary staff required?
5. Were the individuals involved aware that IACUC approval was required before performing the procedures?
6. Has the investigator repeatedly violated IACUC policies? Were the previous violations the same or different than the current action?
7. Was it necessary for the IACUC to intervene to temporarily or permanently interrupt the activities?
(Note: If the answer to this question is yes, the incident must be reported.)
After considering the above questions, the committee members should assess the incident for the following:
1. Have the actions jeopardized the health or well-being of the animals being used or resulted in animals being harmed or dying?
2. Is there evidence that the investigator and/or his or her staff disregarded the institutional animal care and use policy in order to perform procedures without obtaining approval from IACUC?

**Committee Actions**

With regard to reporting requirements, the IACUC may take any of the following actions. (Note: These actions need not be taken sequentially.)
1. verbal warning to the investigator
2. written warning to the investigator without copying the investigator’s departmental chair
3. written warning to the investigator with a copy to the investigator’s departmental chair.

Although judgment must be rendered on a case by case basis, prior experience with reporting incidents to OLAW suggests that the following guidelines are consistent with the philosophy of institutional self regulation.
1. If there was intent to circumvent IACUC authority and animals were harmed in some manner, the committee should report the incident to OLAW.
2. If there was no intent to circumvent IACUC authority and animals were not harmed in some manner, the committee should consider issuing a warning to the investigator but is not required to report the incident to OLAW. {May need to be revised based on the 2/25/05 OLAW guidance.}
3. If there was intent to circumvent IACUC authority but animals were not harmed in some manner, the committee should consider issuing a warning to the investigator prior to or in addition to reporting the incident to OLAW. {May need to be revised based on 2/24/05 OLAW guidance.}
4. If there was no intent to circumvent IACUC authority but animals were harmed in some manner, the committee should consider issuing a warning to the investigator prior to or in addition to reporting the incident to OLAW. {May need to be revised based on 2/24/05 OLAW guidance.}

**Adequate Veterinary Care (Animal Welfare Act 2.33)**

(a) Each research facility shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance with this section:

1. Each research facility shall employ an attending veterinarian under formal arrangements. In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility;
2. Each research facility shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use; and
3. The attending veterinarian shall be a voting member of the IACUC; Provided, however, That a research facility with more than one Doctor of Veterinary Medicine (DVM) may appoint to the IACUC another DVM with delegated program responsibility for activities involving animals at the research facility.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:

1. The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter;
(2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care;

(3) Daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian;

(4) Guidance to principal investigators and other personnel involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia; and

(5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.

Appendix A


