Supervised Staff Training Document

Purpose
This document provides a basic overview of the regulations applicable to research and teaching involving animals and serves as a training tool that must be read and signed by all Category 1 Personnel employed or participating on a project.

Definitions and Requirements
Category 1 Personnel are those whose contact is limited to activities such as teaching laboratories or whose work duties involve animal husbandry (e.g., feeding animals, cleaning facilities, exercising animals, providing enrichment, etc.), performing procedures related to research that do not require handling of the animal without supervision (i.e., pushing a button, checking waters, urine collection without a catheter, recording observational data, etc.), or performing research procedures while directly supervised.

The investigator should provide training, either through self-instruction or through resources available from the Office for Responsible Research or Laboratory Animal Resources (LAR), for all training requirements listed at the bottom of the Certification form on page 6 of this document. Training should be documented and investigators should maintain a copy of the training document in their files for three years past the end of the study.

Category 2 Personnel are those who are performing research-related procedures on animals without direct supervision, are designated as an investigator on a research protocol, or are providing instruction using animals.

Category 2 Personnel must take the online training entitled Working with the IACUC, which can be found on the IACUC Training web page. Effective January 1, 2009, all investigators and key personnel in this category must be listed in the application for IACUC approval and have this training documented before IACUC approval will be released.

In addition, federal regulations require Category 2 Personnel to have species-appropriate training for the animals used in their research or teaching. Species-specific training is available at the URL given above, also. Alternatives (i.e., hands-on training) to the species-specific online training are available through the Office of Laboratory Animal Resources (4-8507) and through videos provided on the IACUC website.

If the species-appropriate training is not online, LAR should be contacted. In special circumstances, the investigator may provide the training if all of the following topics are included: handling, euthanasia, anesthesia, analgesia, and aseptic surgery. Investigators should contact the IACUC to obtain approval before using this method.
Investigators should submit documentation verifying training to the Office for Responsible Research (ORR). The ORR maintains a database of all Category 2 Personnel training, including training provided by LAR.

**Use of Animals in Research and Teaching**

The use of animals in research, teaching, and testing is governed by the Animal Welfare Act, the Public Health Service (PHS) Policy, USDA regulations, and other guidelines.

The Animal Welfare Act (AWA) is a federal law that regulates the transportation, purchase, husbandry, and management of animals used or maintained by the institution. The AWA applies to all warm blooded vertebrate animals except: purpose bred rats, mice, and birds; and livestock used in food and fiber teaching and research.

The Public Health Service Policy applies to live vertebrate animals used in teaching or research funded by a member agency of the Public Health Service. The institutional policies, facilities, veterinary care and animal care programs to be used in these projects are described in the *Guide for the Humane Care and Use of Laboratory Animals*.

USDA regulations, based on a 1985 amendment to the AWA, went into effect between October 1989 and 1991.

The Federation of Animal Science Societies developed the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching* to provide recommendations regarding use of agricultural animals in research and teaching. “Agricultural animals include warm blooded animals used in research or teaching designed to improve understanding of the animal’s use in production agriculture and that may require a simulated or actual production agricultural setting consistent with consideration of the animal’s well-being.” There are also nonprofit organizations, such as the Association for Assessment and Accreditation of Laboratory Animal Care, that promote the humane treatment of animals in science through voluntary accreditation and assessment programs.

Iowa State University must meet the requirements of each of these regulations and take into consideration the various guidelines when establishing policies and procedures regarding use of animals in research and teaching.

**Institutional Oversight**

The regulations and guidance require that each institution have a well functioning animal care and use program with clear lines of authority and responsibility. The program must include

- a properly composed and operating Institutional Animal Care and Use Committee (IACUC);
- procedures for self-monitoring;
- a veterinary care program that provides for the health and well-being of animals and addresses the environmental, housing, and management needs of each animal species;
- an occupational health and safety program (not required under the AWA);
- personnel training; and
- appropriately maintained facilities for housing and support.
An effective animal care and use program also requires active participation by principal investigators, faculty, students, and staff.

**The Institutional Official**
Each institution must have an institutional official (IO) who has legal responsibility for the animal care and use program at the institution. The IO must have the organizational authority to commit the institutional resources and support necessary to maintain a functioning program. The IO or their designee also has the authority to suspend a research activity. The IO for ISU is the Vice President for Research and Economic Development (VPR/ED).

**Office for Responsible Research**
The Office for Responsible Research (ORR) assists the VPR/ED with compliance of its mandates. The ORR plans, develops, modifies, implements, and monitors a comprehensive compliance program for research administration. The ORR also develops and implements research compliance policies and procedures as needed.

The ORR Research Monitor assists investigators in performing compliance self-monitoring, provides research compliance education and training opportunities for investigators conducting research involving animals, and verifies that no material changes have occurred in approved research projects since compliance committee review.

**The IACUC**
The IACUC has the following responsibilities:
- Review and approve, require modifications in, or withhold approval of proposed activities involving live animals in teaching, research, and testing.
- Review and approve, require modifications in, or withhold approval of proposed changes in previously approved research.
- Review, at least once every six months, the research facility’s program for the humane care and use of animals.
- Inspect, at least once every six months, all of the institution’s animal facilities including satellite facilities.
- Prepare reports of the IACUC evaluations and inspections to the IO, including any recommendations for improvement to any aspect of the animal program, facilities, or personnel training.
- Review concerns involving the care and use of animals at the institution.

The IACUC is authorized to suspend any activity involving animals that is not being conducted in compliance with the AWA, PHS policy, or university policy. Suspension may occur only at a full committee where a majority of the voting members vote to approve the suspension.

The institution may also require additional review of an IACUC-approved protocol; has the authority to prohibit a project from being conducted; and may also suspend, terminate, or impose sanctions on any activity involving animals, regardless of whether it was previously approved by the IACUC. However, no institutional official may approve animal activities or reinstate animal activities that were suspended by the IACUC.

**Attending Veterinarian**
Federal regulations require each institution to have an Attending Veterinarian (AV). The AV has a direct report to the IO. The AV also serves as a voting member of the IACUC.
The AV has authority to ensure adequate veterinary care and to oversee the adequacy of other aspects of animal care and use. Adequate veterinary care includes programs of disease detection and surveillance, prevention, diagnosis, treatment, and resolution. The Attending Veterinarian (or designee) is authorized to enter any ISU facility to conduct inspections of animal facilities and animals to ensure that animal husbandry, sanitation practices, and animal health and research techniques are in compliance with federal statutes, regulations, policies, and guidelines, and applicable University policies and procedures.

The Attending Veterinarian's (or designee's) specific responsibilities are to
1. ensure the availability of appropriate facilities, personnel, equipment, and services to comply with the regulations;
2. implement appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and assure the availability of emergency, weekend, and holiday care;
3. assure daily observation of all animals to assess their health and well-being;
4. provide 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. ensure adequate preprocedural and postprocedural care in accordance with current established veterinary medical and nursing procedures.

Principal Investigator
Principal Investigators (PIs) are responsible for the scientific and technical aspects of a project and are also responsible for compliance with PHS Policy, the AWA, and USDA regulations. To be in compliance, investigators must follow these steps:

- Obtain IACUC approval prior to using animals and prior to implementing changes in the IACUC-approved protocol.
- Ensure research is conducted in accord with the IACUC-approved protocol.
- Comply with institutional policies and procedures.
- Submit documents for continuing review and receive approval of ongoing activities involving animals prior to the continuing review date.
- Ensure that all personnel performing procedures have been adequately trained to perform the specific procedures in which they will be involved.
- Ensure that all personnel have received training on the humane methods of animal maintenance and experimentation, including: the basic needs of each species of animal, proper handling and care for the species of animals used, proper pre-procedural and post-procedural care of animals, and aseptic surgical methods and procedures (as required).
- Ensure that all personnel receive proper training on use of anesthetics, analgesics, and tranquilizers for any species of animals used.
- Maintain documentation of personnel training.
- Ensure that all personnel have completed the Hazard Inventory form and are enrolled in the Occupational Medicine program.
- Consider alternatives to using animals in research and to procedures that can cause more than slight or momentary pain or distress in animals, consistent with sound research design.
- Maintain study records, including the IACUC-approved protocol and letter of approval, for at least 3 years past the end of the funding period or past the end of the use of the animal in a teaching/research environment.
Alternatives—Replacement, Refinement, and Reduction

PHS Policy and the animal welfare regulations require that research institutions ensure that investigators are not unnecessarily duplicating research involving animals, have considered nonanimal methods and alternatives to procedures that can cause more than slight or momentary pain or distress, and use the minimum number of animals required to achieve scientifically valid results. Most commonly used are the “3 Rs”:

- Replacement or utilizing nonanimal models
- Reduction of numbers of animals used
- Refinement or elimination or reduction of unnecessary pain and distress in animals

The Office for Responsible Research also maintains a link to the USDA’s Animal Welfare Information Center to provide assistance to investigators with searching databases for other alternatives.

Reporting Concerns Involving the Care and Use of Animals

Concerns about the care and use of animals at ISU may be reported to

- ISU Confidential Hotline by phone at 866-384-4277 or online via the link found at www.compliance.iastate.edu. The web page is hosted on EthicsPoint’s secure servers and is not part of the Iowa State University website or intranet. Reports may be anonymously submitted to EthicsPoint.
- Institutional Official, Dr. Sharron Quisenberry, 4-1785, sharronq@iastate.edu
- Director, Office for Responsible Research, Jerry Zamzow, 4-3115, jzamzow@iastate.edu
- IACUC Chair, Dr. Steve Ensley, 4-1950, sensley@iastate.edu
- Attending Veterinarian, Dr. Mary Sauer, 4-0266, msauer@iastate.edu
- Any IACUC member. The names of current IACUC members may be obtained by contacting the IACUC/IBC Administrator, 4-9581, sbastyr@iastate.edu.

Any individual who, in good faith, reports an animal welfare concern will be protected against reprisals.

Occupational Medicine Program

The Occupational Medicine program at Iowa State provides medical surveillance and assistance to university employees who work with materials and under conditions that have identified and/or regulated risks. Participation in the Occupational Medicine program will address risks associated with working with animals and meet AAALAC requirements. To enroll in this program complete a Hazard Inventory for Occupational Medical Surveillance form (can be obtained from your supervisor) and return the form to the Department of Environmental Health and Safety (EH&S).

Document History

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<td>Added section on Occupational Medicine.</td>
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<td>October 7, 2009</td>
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<td>Added “or participating” to 1st paragraph</td>
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CERTIFICATION

I certify that I have read the document entitled “Use of Animals in Research and Teaching.”

Printed Name of Employee: __________________________________________________________

Signature of Employee: ______________________________________________________________

Date: _____________________________________________________________________________

Printed Name of Principal Investigator: ________________________________________________

Documentation of Investigator Coordinated Training
and
Enrollment in the Occupational Medicine Program

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*If the species being used in the project changes, the investigator should provide and document training appropriate to the species.