

# **Responsible Conduct in Research**

## **Animal Care and Use Education Module**

Winona State University  
Institutional Animal Care and Use Committee  
(IACUC)

# Introduction

- The Winona State University IACUC recommends review of this module by faculty and staff members and students engaged in research, research training, experimentation, biological testing, classroom exhibits and demonstrations, and related activities involving live vertebrate animals, on-campus or off-campus
- Follow review of the module by completing the Animal Care & Use quiz in D2L Brightspace
- For questions about the module, contact the IACUC Compliance Officer at 507.457.5519 or [bayers@winona.edu](mailto:bayers@winona.edu)

# Introduction (2)

- Regulations on the care and use of animals are complex and in constant flux
- Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) have extensive and sometimes conflicting regulations
- The regulations also require adherence to non-government publications which are revised periodically

# Introduction (3)

- Winona State policy is to comply with applicable provisions of the Animal Welfare Act and other federal regulations related to the care and use of animals in research and teaching, regardless of the source of financial support or oversight for the study
- The HHS Office for the Protection of Research Risks has stated that all animal species must be treated uniformly institution-wide, whether or not the animals are “regulated”

# Definitions

- **Animal (HHS Public Health Service definition)** – any live vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or related purposes
- **Animal (USDA definition)** – 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, testing, experimentation, or exhibition purposes, or as a pet
- **Wild animal (USDA)** – any animal which is now or historically has been found in the wild or in the wild state ... including, but not limited to, deer, skunk, opossum, racoon, mink, armadillo, coyote, squirrel, fox, wolf

# Definitions (2)

- The PHS definition covers all vertebrates including birds, rats, mice, fish, reptiles, amphibians, etc.
- The USDA definition excludes birds, rats, mice, and farm animals
- PHS does not define wild animals but refers to the *Guide for the Care and Use of Laboratory Animals* which states, “the basic principles apply to the use of animals living in natural conditions”
- USDA regulations cover research, testing, or teaching procedures that involve the care and use of animals and any school (except an elementary or secondary school), institution, organization, or person that intends to use live animals in research, test, or experiments

# Definitions (3)

- Most institutions faced with these contradictions in regulations and definitions (including Winona State) adhere to the highest standards and policies that ensure compliance with all the regulations
- Therefore, **animals** refers to all animals, used on-campus or off-campus, including wildlife
- **Activities involving animals** are covered by the IACUC when the animals are used in research, research training, experimentation, biological testing, or for related purposes (HHS); and research, testing, or teaching procedures in research, tests, or experiments (USDA)

# Definitions (4)

There are some exceptions to how activities are regulated:

- If an off-campus field study is strictly observational (defined as not involving an invasive procedure, harm to animal under study, or material alterations in the behavior of the animal under study), then it is not covered by the regulations
- If an on-campus animal is on exhibit for observation only, it is not covered
- If an on-campus exhibit or display animal is removed from its housing for instructional use, or if its environment is manipulated for research or teaching purposes, it is covered by the regulations

# History – Scientists' Role

- In 1946, five veterinarians at Chicago-area research institutions began meetings that led to the establishment of the Animal Care Panel, now called the American Association for Laboratory Science (AALAS)
- There were no federal guidelines or regulations on the care and use of animals in research and teaching until the 1960s
- In 1963, ACP used an NIH grant to develop national standards, resulting in the *Guide for Laboratory Animal Facilities and Care*
- The same year, ACP appointed the Animal Facilities Accreditation Board which became the Association of Assessment and Accreditation of Laboratory Care (AAALAC), the only animal care accrediting agency recognized by HHS

# History – Public Role

- At the same time ACP scientists were developing the *Guide*, Rachel Carson published *Silent Spring* (1962), a book credited with focusing public attention on the environment and welfare of animals in the wild
- Four years later, *Life* magazine published a sensational article, “Concentration Camps for Dogs,” which described conditions at the site of a dealer who supplied animals to researchers with “no questions asked.” The article included a photo of a dog owner re-united with his pet, the identification tag of a research facility clearly visible on the animal’s collar

# History – Government Response

- Public outcry over the *Life* magazine story spurred the U.S. Congress to pass the 1966 Laboratory Animal Welfare Act and assign its implementation to the USDA
- Today called the Animal Welfare Act, it covers far more than research and teaching and includes licensing and regulatory requirements for breeders, dealers, and exhibitors
- In 1971, HHS's National Institutes of Health (NIH) issued its first requirements for institutional assurances of appropriate animal care and use
- HHS Public Health Service (PHS) issued its policy in 1973 that now applies to all departments and agencies within HHS

# History – Government Response (2)

- In 1985, the Health Research Extension Act pushed USDA and PHS to coordinate further regulatory development, required institutions to establish Institutional Animal Care and Use Committees (IACUC), and developed national principles for care and use of animals in research
- The U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, established by the Act, apply to all federal agencies developing animal subject regulations
- The nine principles, in essence, establish a “common policy” for animal care and use

# Principles for Utilization and Care of Animals

- I. Transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131) and other applicable federal laws, guidelines, and policies
- II. Procedures involving animals should be designed and performed with due consideration of relevance to human or animal health, the advancement of knowledge, or good of society
- III. Animals selected for procedures should be of appropriate species and quality and the minimum number required to obtain valid results, and mathematical models, computer simulations, and in vitro biological systems should be considered

# Principles for Utilization and Care of Animals (2)

- IV. Proper use, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practice, is imperative
- V. Procedures that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.
- VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure

# Principles for Utilization and Care of Animals (3)

- VII. Living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, housing, feeding, and care must be directed by a veterinarian or scientist trained and experienced in proper care, handling and use of the species. Veterinary care shall be provided as indicated.
- VIII. Investigators and other personnel shall be qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their training.
- IX. Where exceptions are required to the provisions of these Principles, decisions should not rest with investigators directly concerned, but by an appropriate review group such as an IACUC. Such exceptions should not be made solely for the purposes of teaching or demonstration.

# Minimizing use of animals

Before considering the use of any animals, investigators must minimize animal pain and distress. The “Three Rs” for more ethical use of animals in research, testing, and teaching were first described in 1959:

- **Replacement** – develop methods which avoid or replace the use of animals, such as in vitro systems or computer simulations
- **Reduction** – use methods that limit the number of animals while still allowing researchers to obtain statistically significant data, such as sharing tissues or using instrumentation that improves precision
- **Refinement** – develop methods that alleviate or minimize potential pain, suffering, and distress and that enhance animal welfare, such as minimizing trauma or improving surgical techniques

# Principal Investigator Responsibilities

PIs (faculty, staff, and students) must adhere to the four primary regulations covering animal subjects care and use:

1. PHS Policy on Humane Care and Use of Laboratory Animals (HHS administered)
2. Animal Welfare Act (USDA administered)
3. Guide for the Care and Use of Laboratory Animals
4. American Veterinary Medical Association (AVMA) Panel on Euthanasia

*Deviations may be allowed if PI can justify their use based on appropriate documentation, such as citations of standards in professional publications*

# Principal Investigator Responsibilities (2)

PIs are responsible for the following:

1. Design and preparation of the research and/or teaching plan
2. Submission of the “Protocol for Animal Research and/or Teaching Activities” for IACUC review before securing animals or initiating activities
3. Oversight of housing, feeding, and non-medical care of animals
4. Appropriate euthanasia and disposal of animals
5. Training of students involved in activities using animals
6. Reporting to the IACUC of changes in activities, significant events, and data required for reporting

# Personal Hygiene

Basic hygiene and the proper use of protective equipment are important while working with laboratory animals (for investigators and animals):

- Basic hygiene includes:
  - Keep hands away from face
  - Wash hands thoroughly before and after animal contact
  - No contact lens changing or cosmetic application
  - No drinking, eating or food storage in animal housing or use areas
- Protective gloves and eyewear, lab coats, and any other equipment appropriate to the activity must be used
- All injuries and illnesses must be reported to the supervisor or principal investigator.

# IACUC Authority

- The Institutional Animal Care and Use Committee is an agent of the institution, authorized to act on its behalf. It reports to an institutional official who is legally responsible for compliance with federal regulations.
- Animals to be used in research or teaching may not be acquired and housed on campus, nor activities involving animals initiated, prior to IACUC approval
- Animals may be housed only in facilities that have been inspected by the IACUC, and living conditions must meet regulatory requirements

# IACUC Authority (2)

- Reports of unauthorized animals housed on-campus or of activities conducted without IACUC approval will be investigated. Activities found to be unauthorized will be suspended.
- The IACUC may investigate concerns raised by interested persons, on-campus or off-campus. If warranted, previously approved research may be discontinued.
- Activities reviewed and approved by the IACUC may be reviewed and disapproved by institutional officials. However, officials may not approve any study if it has been disapproved by the IACUC.

# IACUC Membership

- PHS and USDA both require that members with scientific and regulatory experience be appointed to the IACUC
- The IACUC may invited individuals with competence in specific scientific areas to assist, as needed
- One IACUC member must be a veterinarian who provides guidance on care and is responsible for directing a care program and addressing possible problems with animal health, behavior, and well-being. Medical care must be available and provided by a qualified veterinarian.

# IACUC Membership (2)

Most institutions (including Winona State) follow PHS guidelines which require five members, including:

- One Doctor of Veterinary Medicine with program authority
- One practicing scientist experienced in animal research
- One member whose primary concerns are non-scientific
- One member who not associated with the institution in any way; nor may a member of his or her immediate family be so affiliated
- A member may meet more than one of the above requirements, but the IACUC must still have five members

*The USDA requires only three members: a chair, veterinarian, and an unaffiliated individual to represent community interests*

# IACUC Role

- Review the animal care program and inspect all animal facilities every six months; report any deficiencies to institutional officials and federal agencies, as required
- Prepare reports for the institutional official and federal agencies, and maintain records of meetings, protocol reviews, and PI reports
- Review animal use protocols and/or protocol modifications involving animals used in research or teaching, including re-review of protocols every three years
- Investigate concerns involving care and use of animals and suspend or terminate research that does not comply with federal regulations
- Make recommendations to institutional officials concerning any aspect of the animal care and use program

# Animal Care and Use Protocol

The IACUC's paramount responsibility is animal care. It reviews requests to use animals in research and teaching with two general goals:

1. Scientific reliance on animals should be minimized
2. Pain, distress, and other harm should be reduced to the minimum necessary to obtain valid scientific results

The research plan, design, and methodology are reviewed in the context that the use of animals is justified, any pain and distress are justifiable, and animals will receive appropriate care.

# Animal Care and Use Protocol (2)

IACUCs consider nine general criteria when reviewing protocols:

1. Justification for animal use
2. Selection and justification of species
3. Living conditions of animals
4. Application of the principles of replacement (use of alternative models such as computer simulations), reduction (use of minimal numbers), and refinement (use of procedures that produce the least amount of pain or distress)
5. Treatment of pain and discomfort
6. Use of restraints
7. Methods of euthanasia
8. Qualifications of research personnel
9. Occupational health and safety

# The Protocol Form

- At Winona State, protocols are reviewed by full committee review, i.e., the full IACUC reviews new protocol submissions
- A quorum must be present at the review and a majority must vote to approve, require modifications for approval, or disapprove the protocol

# The Protocol Form (2)

The *Guide for the Care and Use of Laboratory Animals* summarizes elements of a protocol form to facilitate IACUC review under both PHS and USDA regulations:

- Rationale and purpose of the proposed use of animals
- Justification of the species and number, with the number justified statistically if possible
- Availability or appropriateness of less invasive procedures, other species, isolated organ preparation, cell or tissue culture, or simulation
- Training and experience of personnel in procedures used
- Unusual housing or husbandry requirements
- Appropriate sedation, analgesia, and anesthesia
- Unnecessary duplication of experiments
- Conduct of multiple major operative procedures
- Criteria and process for timely intervention, removal of animals from the study, or euthanasia if pain or stress are anticipated
- Post-procedure care
- Method of euthanasia or disposition of animals
- Safety of working environment for personnel

# Protocol Review

- The Winona State IACUC protocol form is designed to include all elements recommended in the *Guide* in order to conduct its review in accord with the two general goals and nine criteria
- The IACUC may approve the protocol, request modifications, or withhold approval
- When a protocol is disapproved, the PI may revise and re-submit the protocol and/or request a meeting with the IACUC to provide additional documentation (note that any deviations from regulations require written scientific justifications)
- The Winona State IACUC requires re-review of protocols every three years, in accord with PHS guidelines
- As noted earlier, activities disapproved by the IACUC cannot be approved by other institutional officials; however, those officials may disapprove activities approved by the IACUC

# Animal Care and Use Summary

- Regulations covering the use and care of animals in teaching in research are complex and sometimes conflicting
- Winona State practice is to comply with applicable provisions all federal regulations related to the care and use of animals in research and teaching, regardless off the source of financial support or oversight for the study
- Although specific standards are not established for “cold blooded” vertebrates (snakes, fish, amphibians), PHS recommends that all animal species must be treated uniformly institution-wide, whether or not the animals are “regulated”
- The IACUC is responsible for monitoring care and use of animals on behalf of the institution
- The PI is ultimately responsible for the well-being of animals under his or her care, even if day-to-day care is delegated to others
- The PI is also responsible for adhering to all regulatory requirements; the IACUC can assist by providing regulatory guidance and acting as liaison to federal agencies

# Additional Information and Resources

- National Research Council, *Guide for the Care and Use of Laboratory Animals*
- American Veterinary Medical Association (AVMA), *Guidelines on Euthanasia*
- American Association for Laboratory Animal Science (*AALAS*)
- U.S. Department of Health and Human Services (HHS) Office of Laboratory Animal Welfare (OLAW), *PHS Policy on Humane Care and Use of Laboratory Animals*
- U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service, *Animal Welfare Act (P.L. 89-544)*