Responsible Conduct of Research, Scholarship, and Creative Activities

Use of Animals at Michigan State University

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Objectives

- Understand the responsibilities of the <u>scientist/researcher</u> for the responsible conduct of animal research
- Understand the responsibilities of the <u>attending</u> <u>veterinarian</u> for the responsible conduct of animal research
- Understand the responsibilities of the <u>MSU Animal Care</u> and <u>Use Committee (IACUC)</u> for the responsible conduct of animal research
- Become aware of federal, state, and university regulations and guidelines related to animal research



Objectives, *continued*

- Discuss the importance of the "3 Rs" in animal research, and give an example of each "R"
- Discuss the importance of the "5 freedoms" in animal research
- Understand which types of activities using animals require review and/or approval from the MSU Animal Care and Use Committee (IACUC)
- Describe the training requirements for investigators who do animal research at MSU
- Identify the office or offices at MSU that are concerned with animal research



Quiz

There is no quiz associated with the PowerPoint presentation about "Use of Animals at MSU." Instead please complete the quiz embedded in the Institutional Animal Care and Use Committee (IACUC) tutorial. If your research involves animals, also complete appropriate species specific training and health and safety training. These training courses are described on the IACUC web site at

http://www.iacuc.msu.edu/training.html.

Humane Care and Use of Animals

MSU endorses the following four statements from Office of Research Integrity at the U.S. Department of Health and Human Services:

"Animal research is as carefully regulated as human research, but for different reasons. With humans, regulation stems from the need to assure that the benefits all humans gain from human research do not impose unacceptable burdens on some research participants."

ORI Introduction to the Responsible Conduct of Research (Ch 4), http://ori.dhhs.gov/education/products/RCRintro/c04/0c4.html

"Animals may benefit from the information gained through animal experimentation and some research with animals is conducted specifically for the purpose of improving animal health (veterinary medicine and animal husbandry research)."

ORI Introduction to the Responsible Conduct of Research (Ch 4), http://ori.dhhs.gov/education/products/RCRintro/c04/0c4.html

"But most animal research is conducted primarily for the benefit of humans, not animals. Moreover, unlike humans, animals cannot consent to participate in experiments or comment on their treatment, creating special needs that should be taken into consideration in their care and use."

ORI Introduction to the Responsible Conduct of Research (Ch 4), http://ori.dhhs.gov/education/products/RCRintro/c04/0c4.html

"The special needs of animals have evolved over time into policies for the appropriate care and use of all animals involved in research, research training, and biological testing activities.

Researchers can meet their responsibilities by:

- Knowing what activities are subject to regulation,
- Understanding and following the rules for project approval,
- Obtaining appropriate training, and
- Accepting continuing responsibility for compliance through all stages of a project"

ORI Introduction to the Responsible Conduct of Research (Ch 4), http://ori.dhhs.gov/education/products/RCRintro/c04/0c4.html

- If you expect to use or study living animals in your activities at Michigan State University, regardless of the level of invasiveness,
 - Familiarize yourself with your responsibilities as outlined in this module
 - Contact the MSU Institutional Animal Care and Use Committee (IACUC) at 517-432-8103 or <u>http://www.iacuc.msu.edu</u>



Applicability

- MSU recognizes and embraces the fundamental interdependence of humans and animals and is committed to the core value of humane care and use of all animals
- Information in this module applies to all faculty, staff, and students whose primary appointment is at MSU and/or who will receive a degree from MSU
- The requirements and expectations stated herein apply to all activities involving the use of animals conducted at MSU facilities and/or as a result of contracts, collaborations, and/or consultations at other facilities



Applicability, continued

- Animal-related activities are an integral part of MSU's teaching, research and outreach missions and help MSU advance the quality of life for people and animals
- As a land-grant university, MSU regularly makes its facilities available to individuals and groups from outside the University community who wish to use these facilities for exhibitions, competitions, and other events involving animals, and MSU periodically contracts for programs in which animals perform



Applicability, continued

 MSU takes great pride in the humane treatment its personnel provide to animals in its care and expects the same commitment to animal welfare from others using MSU facilities

Animal Welfare at MSU

- Over 60 species are part of the animal population at MSU, including lab animals, farm animals, and wildlife.
- Campus Animal Resources personnel are available around the clock year round to provide care for the animals on campus. MSU takes pride in a healthy animal population.

All Responsible Use of Animals is Local!

Oversight of Animal Use at MSU

Michigan State University

- Is registered with the <u>U.S. Department of Agriculture</u> as a research facility
- Maintains an Animal Welfare Assurance with the National Institutes of Health <u>Office of Laboratory</u> <u>Animal Welfare</u>
- Is fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (<u>AAALAC</u>)

Animal use is managed in compliance with the:

- <u>Animal Welfare Act</u>
- Animal Welfare Act Regulations <u>Part I</u>, <u>Part 2</u>, <u>Part 3</u>
- <u>Guide for the Care and Use of Agricultural Animals in</u> <u>Agricultural Research and Teaching</u>
- Guide for the Care and Use of Laboratory Animals
- <u>Public Health Service Policy on Humane Care and Use</u> of Laboratory Animals
- <u>U.S. Government Principles for the Utilization and Care</u> of Vertebrate Animals Used in Testing, Research, and <u>Training</u>

For activities conducted in contract, subcontract, and/or collaboration with other institutions, the performance site is expected to:

- Be in compliance with the documents listed on the previous slide
- Have an Animal Welfare Assurance on file with NIH, if such collaborations involve funds from the Public Health Service
- Be accredited by <u>AAALAC</u>
- Foreign institutions must have an NIH Assurance, be in compliance with the <u>International Guiding Principles For</u> <u>Biomedical Research Involving Animals</u>, and/or accredited by AAALAC

- The Animal Care Program at MSU promotes research and teaching by providing excellent animal care and investigator support, within the context of all federal regulations, policies and guidelines
- The president of MSU, Lou Anna K. Simon PhD, has charged the Vice President for Research and Graduate Studies, Steven D. H. Hsu PhD, and the IACUC with the responsibility of oversight and management of the use of animals at Michigan State University. This includes direct and indirect oversight and involves other entities on campus
- Compliance should be a natural expression of the program's concern for animals and science

Direct oversight is provided for:

- Research biomedical, agricultural, social science, natural science, and wildlife research, as well as clinical trials
- Teaching all course work and all activities related to or required for degree completion
- Testing
 - Clinical trials
 - Drugs, compounds, and devices
 - Feed and nutritional supplements
- Other research and educational activities

Indirect oversight is provided for, but not limited to:

- Production husbandry and veterinary care of agricultural animals
- Entertainment and/or exhibits rodeos, circuses, plays, and/or competitions
- Security animals used for police work, as well as sentinel animals on the farms
- Outreach use of MSU and non-MSU owned animals in exhibitions and/or K-12 and other educational programs for the general public
- Other activities as determined appropriate

Oversight of Animal Use at MSU: **Requirements**

An Animal Use Form (protocol) must be reviewed and approved by the IACUC for all:

- Research agricultural, biomedical, veterinary, social science, natural science, and wildlife research; clinical trials; and any activity that involves animals and will be published
- Teaching all course work, as well all activities related to or required for degree completion
- Testing all clinical trials; testing of drugs, compounds, and or devices; and testing of feed or nutritional supplements

Oversight of Animal Use at MSU: **Requirements,** continued

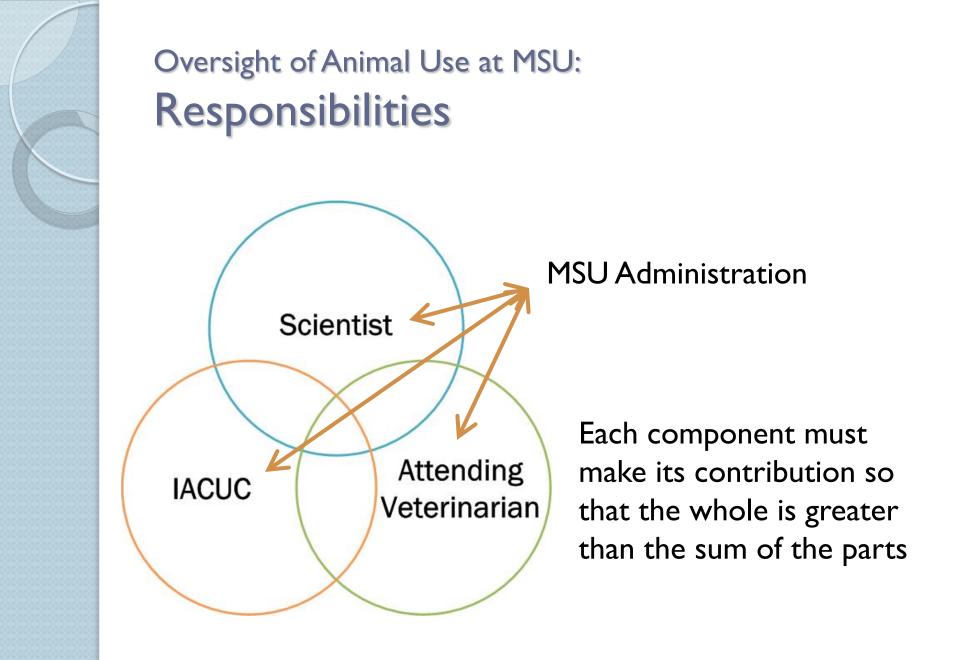
The IACUC reviews:

- Husbandry and veterinary care of agricultural animals (Standard Operating Procedures describing husbandry aspects of agricultural animals are reviewed and approved by the IACUC annually)
- Use of animals for campus security purposes is generally managed by DPPS with consultation with the attending veterinarian and/or IACUC, as necessary
- Outreach which includes MSU as well as non-MSU owned animals in K-12 and or other educational programs for the general public
- Other activities as determined appropriate

Oversight of Animal Use at MSU: **Requirements**, *continued*

The IACUC should be notified of other uses of animals on campus:

- MSU regularly makes its facilities available to individuals and groups from outside the University for exhibitions, competitions, and other events involving animals, and MSU periodically contracts for programs in which animals perform.
- MSU expects a commitment to animal welfare from others using MSU's facilities.
- See the <u>Animal Event Contract Guiding Principles</u> for a more comprehensive description of requirements



Oversight of Animal Use at MSU: Responsibilities of Administration

- Promote the advancement of scientific knowledge
- Foster an environment of trust and communication
- Provide resources for a high quality animal care program
- Ensure training
- Provide mechanism of oversight
- Provide security

Oversight of Animal Use at MSU: Responsibilities of Administration, continued

- General oversight for the use of animals at Michigan State University is charged to Steven D. H. Hsu PhD, the vice president for research and graduate studies.
- Day-to-day oversight is the responsibility of J.R. Haywood PhD, the assistant vice president for regulatory affairs.

Oversight of Animal Use at MSU: Responsibilities of the Attending Veterinarian

- Ensure adequate and proper animal care and use
- Provide oversight and consultation for veterinary care of all animals at Michigan State University
- Work in concert with the IACUC and scientists towards optimal animal care and use
- Exercise professional judgment to facilitate the science in the context of animal welfare

Oversight of Animal Use at MSU: Responsibilities of the Attending Veterinarian, continued

Michigan State University's Attending Veterinarian is F. Claire Hankenson, DVM, MS, DACLAM

She is assisted by:

- N. Kent Ames, DVM, MS
- Danielle Ferguson, DVM, MS
- 2 veterinary technicians
- More than 30 animal care staff

Oversight of Animal Use at MSU: Responsibilities of the IACUC

- Protect the institution and the research
- Implement regulations using scientifically sound, performance-based standards
- Work with faculty, staff, and students to ensure the humane care and use of animals
- Assure the public of quality animal care

Oversight of Animal Use at MSU: Responsibilities of the IACUC, continued

The IACUC at Michigan State University:

- Is chaired by Susan Barman PhD, professor of Pharmacology and Toxicology
- Has over 18 members including scientists, nonscientists, faculty, staff, and students, including 3 individuals not affiliated with the University to provide a community perspective and oversight
- Is staffed by Sally Light, Candy Flynn, Sandy Wilkins, and Monique Bauer

- Accept personal responsibility for the humane care and use of animals at Michigan State University
- Understand that it is a privilege to be able to use animals as research and teaching subjects
- Respect the contribution of animal subjects to the body of knowledge
- Engage in the IACUC process, perhaps even as a member the MSU IACUC includes 14 scientific members representing the various colleges in which animals are used
- Know the regulations
- Plan activities in the context of quality animal care
- Write meaningful animal use protocols

Employ the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training when planning activities and writing animal use protocols:

 "Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society."

Employ the government principles when planning activities and writing animal use protocols:

- "The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered."
- "Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative."

Employ the government principles when planning activities and writing animal use protocols:

- "Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals."
- "Procedures with animals 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."

Employ the government principles when planning activities and writing animal use protocols:

 "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."

U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training,

http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples

Oversight of Animal Use at MSU: Responsibilities of Scientists, continued

When considering your use of animals, remember to apply the 3 Rs:

- *Reduce* ... the number of animals used in research
- *Refine* ... the endpoints and procedures of the experiment to eliminate and/or alleviate pain and distress
- *Replace* ... animals with non-animal models whenever possible

Oversight of Animal Use at MSU: Responsibilities of Scientists, continued

When considering your use of animals, remember to apply the 5 freedoms within the context of your research and teaching activities:

- From hunger and thirst
- From discomfort
- From pain, injury, or disease (unrelated to the activity at hand)
- From fear and distress
- To express the most "normal" behaviors characteristic of the animal species

Oversight of Animal Use at MSU: For Activities Using Animals - Overview

- Submit Animal Use Forms (AUF) prior to conducting the activity
- Request assistance from the IACUC Office
 - To confirm required paperwork and/or documentation
 - For information about transferring protocols and/or grants to MSU
- IACUC contact information

iacuc@msu.edu http://www.iacuc.msu.edu (517)423-8103

- Required paperwork must be submitted to, reviewed, and, if required, approved by the IACUC before animal use activities can begin
- The attending veterinarian and/or designee, is to be consulted in the design and/or modification of any study which includes the potential for pain and/or distress

- All modifications and/or amendments to approved activities must be submitted to, reviewed, and approved by the IACUC before implementation of any changes
 - Pls are allowed to use professional judgment in the conduct of research projects with the caveat that procedures and activities cannot be added or significantly modified without prior approval by the IACUC
- PIs must submit an annual renewal to insure that all activities are re-reviewed at least annually, within a year from the last approval date

 All individuals actively engaged in the project must be appropriately trained and qualified as determined by the IACUC before they work with animals. See

www.iacuc.msu.edu/training.html.

- All personnel who work with animals are to be enrolled in the occupational health and safety program. See <u>www.orcbs.msu.edu/animal_handler/animal_handler_toc.htm</u>
- All facilities where animals are used and/or housed are subject to at least annual inspection by either the USDA, the IACUC, AAALAC, and/or an agent of these entities.

- All activities are subject to at least annual post-approval monitoring to compare ongoing activities with those described in the approved paperwork.
 - Conduct of activities other than as described in an approved protocol is not allowed.
 - For PHS-funded activities, the IACUC is required to notify the funding agency of non-compliance.
 - The IACUC is authorized to suspend non-compliant activities; suspensions must be reported to the NIH, USDA, and any applicable federal funding agencies.
 - Federal funds, including salary support, cannot be expended for non-compliant activities.

Oversight of Animal Use at MSU: If You Are Involved In An Activity Using Animals, It Is Your Responsibility To:

- Determine that the activities have been approved by the IACUC before animal use activities begin. A copy of the IACUC approved protocol should be readily available from the principal investigator.
- Determine that any modifications and/or amendments to approved activities are approved by the IACUC before implementation of any changes. A copy of the IACUC approved modification/amendment should be readily available from the principal investigator.

Oversight of Animal Use at MSU: If You Are Involved In An Activity Using Animals, It Is Your Responsibility To:

- Complete the <u>training requirements</u> before working with animals.
- Complete the <u>occupational health and safety</u> <u>requirements</u> before working with animals.

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Reporting Concerns

- It is your responsibility to report concerns about use of animals in research, teaching, and outreach
- Report concerns to:
 - The IACUC at 517-432-8103
 - Interim Attending Veterinarian, Dr. F. Claire Hankenson at 517-432-4242
 - Campus Animal Resources at 517-353-5064
 - Farms Veterinarian at 517-719-6165
 - After hours, weekends, and holidays, University Police at 517-355-2222

Reporting Concerns, continued

- Reports will be reviewed promptly by the animal care program management, in compliance with USDA and NIH requirements
- Persons reporting may do so anonymously and without fear of reprisal in accordance with the federal Animal Welfare Act

Good Animal Care and Good Science Go Hand-in-Hand

FASEB Statement of Principles for the Use of Animals in Research, Teaching and Testing

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For More Information @ MSU

- Resources
 - Institutional Animal Use and Care Committee <u>http://www.iacuc.msu.edu</u>
 - Campus Animal Resources
 <u>http://www.animalresources.msu.edu</u>
 - Office of Regulatory Affairs <u>http://www.ora.msu.edu/</u>
- Questions may be directed to:
 - The IACUC at 517-432-8103
 - Campus Animal Resources at 517-353-5064
 - Office of Regulatory Affairs at 517-432-4500

Sources

- IACUC 101[™] Resource Manual, James, ML, editor.
 October 2009.
- Essentials of IACUC Administration Resource Manual, Greene ME and ME Pitts, editors. PRIM&R, September 2009.
- Steneck, NH. (2006, web version). The Welfare of Laboratory Animals (Chapter 4), ORI Introduction to the Responsible Conduct of Research, Office of Research Integrity, U.S. Department of Health and Human Services, <u>http://ori.dhhs.gov/education/products/RCRintro/c04/0c4.html</u>

Sources, continued

- U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, <u>http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples</u>
- Guide for the Care and Use of Laboratory Animals. (1996). National Academy Press, <u>http://www.nap.edu/catalog.php?record_id=12910</u>
- Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. (1999). Federation of Animal Science Societies,

http://www.fass.org/page.asp?pageID=216