CRR: Animals in Research

Compliance Risk Areas

Compliance Risk Areas	Related Governing Laws, Rules, Regulations, or University Policies
• Permit requirement to buy and sell listed animals or register for their use by dealers of animals, exhibitors of animals, and research facilities that use listed animals. • Limitations/regulations on how animals may enter the controlled chain of commerce, to eliminate the use of stolen animals. • Limitations/regulations on the environmental conditions under which the animals must be kept. • Requirement for research facilities to purchase listed animals only from licensed dealers. • Transportation of included animals must comply with published regulations governing the well-being of the animals. • Research facilities must create an Animal Care Committee to review the use of animals by the facility and inspect the animal housing facilities. • Research facilities must abide by legal	• Animal Welfare Act 7 U.S.C. §§ 2131-2159 9 C.F.R. §§ 1-4

restrictions on the imposition of pain during research. • Research facilities must comply with extensive regulations concerning the housing and care of animals used in research. • Illegal for any person to knowingly sponsor or exhibit an animal in any animal fighting venture • Insure that animals intended for use in research facilities or for exhibition purposes or for use as pets are provided humane care and treatment • Assure the humane treatment of animals during transportation in commerce • Protect the owners of animals from the theft of their animals by preventing the sale or use of animals which have been stolen.	
• Animal welfare assurance • IACUC Committee functions • Review of PHS conducted or supported research projects • Record keeping requirements • Reporting requirements	• PHS – Humane Care and Use of Laboratory Animals
• Consideration of alternatives to animal use in research	• APHIS Animal Care program (US Dept of Agriculture)– conducts inspections
• Proper treatment of animals including adequate veterinary care;	• Code of Federal Regulations Title 99, the Health Research Extension Act of

and organization and operation of IACUC	1985
• Points to the Guide for Care and Use of Laboratory Animals	• Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training
• Have clearly established lines of authority and responsibility • Have an active IACUC • Have procedures for self-monitoring of the IACUC through semi-annual review of programs and facility oversight by the institutional officer • Appropriate maintained facilities for proper management, housing and support of animals • Adequate program of veterinary care • Training and occupational health programs for individuals who work with animals • Must develop policies for animal care and use related to research conducted off site as well as research using privately owned animals on and off site. • Adopt an immunization schedule	• Federal of Animal Sciences Societies' Guide for the Care and Use of Agricultural Animals
• Procedures to be designed and performed with due consideration for their relevance to human or animal health, the advancement of knowledge, or the good of society	• Board of Regents Policy: Animal Care and Use

• The proper use of animals requires avoidance or minimization of discomfort, distress, and pain. • Staff involved in the care and use of animals shall be qualified or supervised, meet all required training, enroll and participate in an occupation health program as required, and abide by and carry out the decision of the IACUC.	
• Veterinarians may prescribe extralabel uses of certain approved new animal drugs and approved human drugs for animals under certain conditions. • Any drug prescribed and dispensed for extralabel use by a veterinarian or dispensed by a pharmacist on the order of a veterinarian must bear or be accompanied by labeling information adequate to assure the safe and proper use • FDA may prohibit the extralabel use of an approved animal drug or class of drugs in food-producing animals under certain conditions.	• Animal Medicinal Drug Use Clarification Act of 1994 (public Law 103-396)
• Covers areas; use of laboratory animals, IACUC programs; environmental management and housing; veterinary care	• National Research Council's Guide for the Care and Use of Laboratory Animals
• University faculty, staff, and students using potentially hazardous biological	• Board of Regents Policy: Activities involving Recombinant and Synthetic

agents in research or teaching activities shall perform those activities in ways that eliminate or reduce potential exposure to personnel, students, animals, and the environment.	Nucleic Acid Molecules or other Potentially Hazardous Biological Agents

General compliance questions for each risk area

1. How is compliance in this area monitored and how frequently?
2. What are the current compliance risks in this area (lack of monitoring, lack of resources, education, etc.)?
3. Explain any audit findings (federal, state, internal, etc.) from the past three years.
4. What are the emerging compliance risks in this area? Is yes, please explain.

Cost of Compliance Measurement Questions

1. How many employees (FTEs) are dedicated to compliance-related activities in this area?
2. What is spent annually, on average, to perform the compliance-related activities conducted by this unit? Please include only those items that require the purchase or goods or services from an outside entity such as outside consulting services, equipment purchases, non-routine supplies, or fees.
3. Please list all training required to maintain University compliance in this subject area. For each training requirement:
    a. Identify the primary source of the requirement as (1) federal law, (2) state law, (3) administrative regulations, or (4) University policy.
    b. Identify categories of employees (e.g., faculty, P&A, etc.) required to take the training.
    c. Estimate the number of employees in each category required to take the training.
    d. Identify the frequency (e.g., quarterly, annually) and the length of the training (e.g., 1.5 hours)

4. Estimate the number of employees system-wide who are subject to the compliance requirements in this area.
5. Excluding time required to meet training requirements addressed in Question 3 above, please estimate the time required annually for these employees to comply with other compliance requirements (e.g., record keeping, monitoring, testing, reporting).

Animal Care Committee

1. How many are external IACUC committee members are there, and who are the current external (to the University) members are on the committee?
2. Which on the committee has primary concerns in a nonscientific area, such as ethicist, lawyer, or member of the clergy, and what are their primary concerns?
3. What training is required for IACUC members, and does this required training occur prior to participating in IACUC meetings or inspections?
4. How is it determined that an IACUC member has a close family relationship with an individual who is one of the investigators or who has a significant financial or managerial interest in a sponsored entity or product being evaluated?

Reviews

1. Please provide a copy of the current Animal Welfare Assurance document that was last submitted to the Office of Laboratory Animal Welfare.
2. Please provide a copy of the last review results and certification provided to the Director of NIH.
3. What is the number of active research projects involving animals at any given time?
4. What is the frequency for conducting review of existing animal protocols?
5. Specify the frequency of the review and care and treatment of animals in all study areas and facilities. Indicate the percentage of animal study areas and facilities that are completed on an annual basis.
6. Indicate how scientists and other personnel receive instruction or training in the area of animal care and treatment, and the frequency of such instruction. How is there assurance that all required personnel receive this instruction or training? How is it

ensured that investigators and other personnel are appropriately qualified and experienced for conducting procedures on living animals (e.g. in-service training).

7. Who confirms whether or not due consideration is given to alternatives that would not require animal use in research, when viewing a protocol/proposal?
8. When the committee determines that a significant deficiency of the regulations has occurred:
    a. how is the incident documented;
    b. to whom is it communicated and within what time period (e.g., X weeks);
    c. and what is the typical timing for correcting the deficiencies.
9. Who is responsible for the follow-up on the significant deficiencies, and how soon does that follow-up occur related to the schedule for corrections?
10. Over the past three years, how many serious or continuing noncompliance circumstances have been reported to OLAW or IACUC suspensions.
11. How many occupational health and safety incidents have been reported this past year in conjunction with working with animals? What measures were taken post-incident to reduce the possibility of a recurrence?
12. Provide two recent examples of documentation related to support that alternative to procedures that may cause more than momentary or slight pain or distress were not available.
13. What measures are taken when patterns of problems arise for a particular unit/area?
14. When and how frequently are the postoperative and post-procedural analgesic regimens in protocols reviewed and by whom?

Housing of animals

1. How many animal housing facilities exist across the University system?
2. How frequently are the animal housing facilities (buildings, rooms, areas, enclosures) inspected, and by whom?
3. Does the type of funding (e.g., federal vs other) influence the frequency and nature of the physical inspections, and if yes, how?

4. What has been the volume and nature of issues with animal housing facilities over the past two years?

Care and treatment

1. At what point and by whom are disaster plans created for a facility? When are the plans reviewed, approved, and updated?
2. Please provide a copy of two separate disaster plans that are currently in effect.
3. Please provide a copy or a link to the University's immunization plan.
4. What percent of medical care provided to animals, over the past two years, has been handled by a qualified veterinarian?
5. Has the IACUC suspended an activity involving animals any time in the past two years?

Procurement and transportation of animals – Research Animal Resources (RAR)

1. How is it ensured/known that all animal purchases for research have been procured through RAR? Have you encountered any violations of this process? If yes, what steps were taking both for that project and for future projects for that unit/PI?
2. How many vehicles are there transporting animals and what is the frequency of the inspections of those vehicles?
3. Are all RAR personnel holding an animal use certification prior to gaining access to facilities managed by RAR? What training records are kept to coincide with the hire date?

Risk Area – Environment enrichment

1. In what way is RAR informed/educated on the appropriate environment enrichment by type of animal?
2. Do inspections always include confirming the appropriate environment enrichment exists?