

TITLE: IACUC Enforcement Policy for University of Arizona Animal Hazards Program

PURPOSE: To reduce the health risk of using animals in research and teaching to an acceptable level.

REVIEW/REVISIONS:

Permanent amendment/revisions to this policy must be presented to the IACUC for review before implementation and should be developed in consultation with the following: IACUC membership, Occupational Health personnel, Animal Hazards Program Committee.

EFFECTIVE DATE: 11/22/00; **Revisions/Re-Approval:** 3/22/01, 9/29/05, 11/2/06, November 1, 2007

POLICY/PROCEDURES:

Registration Requirements:

All persons participating on any IACUC reviewed/approved projects or accessing animal facilities must be registered with the Animal Hazards Program. This is accomplished by completion of a Risk Assessment Questionnaire (RAQ). The RAQ may be completed on the Occupational Health Clinic's Animal Hazards web page:
http://www.health.arizona.edu/webfiles/health_services_animal_hazards.htm.

Note: *Persons without a Risk Assessment Questionnaire on file with the Occupational Health Clinic will not be eligible for facility access or participation on any animal-related protocol.*

Contact Requirements:

Every lab will have one individual that serves as the Occupational Safety Designee (OSD). This individual, along with the Principal Investigator is responsible for occupational safety concerns for their research group. Protocol forms provide a space for PIs to indicate their OSD.

Note: *Any protocols submitted without a specified Occupational Safety Designee (OSD) will not be routed for IACUC review.*

Training Requirements:

Dr. Michael Rand of University Animal Care has developed a training program that will be scheduled in conjunction with the regular IACUC Certification Classes. Introduction to Animal Hazards Program is also available online at <http://www.iacuc.arizona.edu/training/>

Please note that these classes are to be considered as much a requirement as the other IACUC classes – The Animal Hazards Program is the means by which the University of Arizona and the UA-IACUC have elected to comply with federally mandated requirements.

All persons participating on any IACUC reviewed/approved projects must attend the Introduction to Animal Hazards Program class.

OSD Requirements: The OSD for each research group is responsible for assuring that all members of the research group are adequately informed of, and receive training in Occupational Safety issues. This Occupational Safety Designee (OSD) will need to attend all species specific classes on zoonotic diseases that are germane to the specific areas of research undertaken by the research group. The PI and OSD may choose how best to train members of the individual research

group in these issues, which may include their also taking the zoonotic disease classes.

Note: *Any individual who does not have certification in Introduction to Animal Hazards Program will not be authorized to participate on protocol or have facilities access.*

Animal Hazards Program Care Plan:

- a. The Risk Assessment Questionnaire must be updated whenever an employee changes jobs or animal species, or as deemed necessary by the Animal Hazards Committee or Occupational Health.
- b. The questionnaire will be reviewed by the Occupational Health Service and a clinic visit may be scheduled depending on level of risk or in accordance with specific job requirements. If not otherwise required, individuals may decline the clinic visit, but must file a formal declination with Occupational Health. This information will be forwarded to the OSD or supervisor for their records.
- c. The recommendations made by the provider at the visit will be based on the functional requirements of the position, the type of animal contact, and the individual’s medical history. Any persons declining to obtain recommended inoculations or testing will be required to sign a declination form. This information will be forwarded to the OSD or supervisor for their records.

Non-Compliance:

Persons will be deemed non-compliant if they refuse to complete a Risk Assessment Questionnaire, or do not file appropriate declination forms.

In the event that an individual is designated “Non-Compliant” the following actions will be taken:

- 1) A letter from Occupational Health will be forwarded to the individual, their OSD or Supervisor, and the Institutional Animal Care and Use Committee (IACUC) Office informing them of the person’s non-compliant status.
- 2) The Institutional Animal Care and Use Committee (IACUC) will review the case and the following consequences may be assessed:
 - a) No new or renewal protocols or amendments will be reviewed for that individual.
 - b) A hold may be imposed on protocols for animal ordering.
 - c) Facility access may be withdrawn.
 - d) The individual may be required to attend a convened meeting with the IACUC.
 - e) Protocols may be suspended.

Non-Participation:

- 1) Non-participation is designated when an individual, who is not otherwise required to participate by specific job requirements, may formally file a declination form indicating their decision not to participate in certain aspects of the program:
 - a) Clinic Visit
 - b) Obtain recommended immunizations or tests recommended by their animal hazard category.
- 2) Non-participation is not an option for individuals working with primates, in studies involving potential rabies exposure, or as otherwise mandated by the IACUC or their supervisor.

Exemption:

Individuals who do not work with animals or animal materials in the laboratory, classroom or field are exempt from participation unless otherwise directed by their supervisor.

Inspection Requirements:

The University of Arizona Animal Hazards Program requires annual documentation of inspection for all investigators' study areas for occupational health and safety hazards (AHP Section X.A.1). Utilizing the University of Arizona Animal Hazards Program Health and Safety Inspection Checklist and Report Documentation, each research group, as identified by Principal investigator, must perform an inspection of their work areas to identify and minimize health and safety hazards. These inspections are to be performed by the research group's Occupational Safety Designee, plus at least one other individual as identified in the Animal Hazards Program (AHP Section X.E.1.a). The University of Arizona Animal Hazards Program Health and Safety Inspection Report Form must be completed and the Identified Hazard Summary Sheet with the Signature page must be filed with the IACUC Office at a date to be specified by the IACUC in conjunction with the Semi-Annual Spring Inspections. New Investigators, who have not commenced with animal work by the time the inspection reports are due, will be allowed to waive the requirement for one year.

Note: Principal Investigator who do not file the University of Arizona Animal Hazards Program Health and Safety Inspection Report Documentation as required:

- 1) Will not have subsequent protocol submissions reviewed until such time as the report has been filed.
- 2) Will have a hold imposed on all their protocols for animal ordering.

PIs will be allowed an additional two week period to become compliant, or provide acceptable written justification for why they need longer, before all facilities access for their research group (as identified in their protocols as participating personnel) will be deactivated in order that animals already on study will not be wasted.

Follow-Up Action:

In the event that an individual is found in the facility after having their access withdrawn for being non-compliant, the PI will be required to attend a convened IACUC meeting to discuss this issue. If a satisfactory conclusion is not arrived at, all the PI's protocols may be subject to suspension, which would also require notification to the granting agency.

JUSTIFICATION:

Requirements for an occupational health program for personnel working with laboratory animals are found in *Biosafety in Microbiological and Biomedical Laboratories* published by the Centers for Disease Control and Prevention and the National Institutes for Health; Code for Federal Regulations, Title 10, Part 20 and Title 29, Part 1910; the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* that codifies the *Guide for the Care and Use of Laboratory Animals* published by the National Research Council; and, *Occupational Health and Safety in the Care and Use of Research Animals* published by the National Academy of Sciences. A description of the occupational health program must be included in the Assurance of Compliance that is required by the National Institutes of Health. Triennial inspections are conducted by the Association for the Assessment and Accreditation of Laboratory Animal Care, International to assure compliance with all applicable occupational health and safety standards.

Under the standards outlined in the *Guide* the program components must include:

- * Hazard Identification and Risk Assessment
- * Personnel Training
- * Personal Hygiene
- * Facilities, Procedures, and Monitoring
- * Personal Protection

* Medical Evaluation and Preventive Medicine

This enforcement policy addresses primarily the first two components listed above: Hazard Identification and Risk Assessment, and Personnel Training.

As directed by the Vice President for Research, the IACUC has delineated sanctions for non-compliance with specific elements of the Animal Hazards Program. It should be noted that upon written verification of compliance with these requirements, sanctions will be lifted.

The full explanation for the Animal Hazards Program can be found at:

<http://www.iacuc.arizona.edu/animalhazardsprogram.shtml>