FLORIDA ATLANTIC UNIVERSITY

Division of Research

SUBJECT:	**Effective Date:**	**Policy Number:**
Animal Research Involving Hazardous Materials	September 24, 2021	10.4.9
	Supersedes: October 26, 2018 March 25, 2005	**Page** **1** **of** **6**
	Responsible Authorities: Principal Investigator Vice President, Research Institutional Animal Care and Use Committee Assistant Vice President for Research, Research Integrity Assistant Vice President for Research, Comparative Medicine	

I. Background

Federal and state requirements including the Guide for the *Care and Use of Laboratory Animals* pertaining to the use of hazardous materials in research require that Florida Atlantic University's IACUC review the use of hazardous materials proposed in research, teaching or testing endeavors using vertebrate animals.

II. Purpose

Hazardous materials are strictly controlled by federal, state and local regulations. Institutions have specific policies regarding the use of hazardous materials. The Office of Environmental Health and Safety approves and oversees the use of hazardous materials at FAU. Additionally, Florida Atlantic University has established specific safety committees composed of professional staff and faculty with expertise in handling specific types of hazardous materials. These committees include the Institutional Biosafety Committee and the Radiation Safety Committee. The purpose of this policy is to ensure the appropriate approvals and safety committee review (if applicable) and assess potential hazards proposed in research using animals.

III. General Statement

This policy is applicable to all research involving the use of hazardous materials in animals conducted under the auspices of Florida Atlantic University (FAU)'s animal care and use program and applies to field studies as well as all campus locations.

IV. Policy

Many research studies with vertebrate animals require the use of drugs, chemicals, radioisotopes, biological agents, toxins and/or other substances that pose potential threats to animals and/or human health. All substances that will be used in animals or animal facilities must be described within the animal care and use protocol form. As each protocol is reviewed, hazards are identified and, when necessary, additional safe practices are put in place. Hazard review is typically conducted by Environmental Health and Safety (EH&S) and may include veterinarians, IACUC members, the Radiation Safety Committee and the Institutional Biosafety Committee (IBC). If required, approval must be obtained from all relevant departments and/or committees prior to starting any hazardous work with animals. Changes in hazard use must be approved by the IACUC and relevant oversight bodies prior to implementation.

V. Definitions

A. **Hazardous Materials** are those materials that constitute a hazard to animals, humans or the environment. For the purpose of this policy, the specific hazardous materials are listed below:
   - Agents requiring handling conditions above Biosafety Level 1 (BSL1)
   - Agents infectious to animals requiring handling conditions above Animal Biosafety Level 1 (ABSL1)
   - Biological specimens (e.g. saliva, blood and urine) collected from humans and non-human primates
   - Biological toxins (e.g. Botulinum toxin including cosmetic BOTOX) used in conjunction with animals
   - Chemicals designated by the National Institute of Occupational Health (NIOSH) such as hazardous drugs, carcinogens, reproductive hazards, nanoparticles, or toxic chemicals as well as materials that may have serious impact on the environment during release or disposal that are used in conjunction with animals
   - Activities involving recombinant or synthetic Nucleic Acid Molecules (recombinant DNA or rDNA)
   - Activities involving any radiation producing equipment or materials including ionizing, non-ionizing, x-rays and lasers
   - HHS and USDA Select Agents and Toxins as defined in Federal Regulations 7CFR 331, 9CFR 121 and 42CFR 73. The current list is available at https://www.selectagents.gov/SelectAgentsandToxinsList.html

B. **Biological Hazards/Biohazards** commonly refers to agents or materials of biological origin that are potentially hazardous to human, other animals, or plants. These could include (but are not limited to) infectious agents, materials containing recombinant DNA molecules, toxins of biological origin and human (or non-human primate) derived materials.

C. **Radiological Hazards** Radiation (ionizing radiation) means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high speed protons and other particles capable of producing ions. The level of hazard is determined by the amount of radiation, type of radiation, chemical form, method of use (procedures and protocols) and other factors.

D. **Personal Protective Equipment (PPE**) is a device or garment worn by the researcher to protect against hazards. Example of PPE include such items as gloves, eye protection, face shields, masks, protective hearing devices, respirators. Please see FAU IACUC policy 10.4.16 Access Control and PPE for more information.

VI. Accountability

The Principal Investigator (PI) will be responsible for:

- Complying fully with this policy on hazardous material use involving animals.
- Submitting the appropriate forms for review to the appropriate safety committee as well as to complete the appropriate section in the animal use protocol form. The PI must attach final approval from the appropriate safety committee (e.g. IBC or Radiation Safety Committee) to the IACUC form. Final approval of the animal use protocol is dependent on receipt of the relevant safety committee approval.
- Informing Comparative Medicine and EH&S staff prior to using hazardous materials with animals.
- Flagging all cages with Hazard Cage Cards to identify cages that have been treated with hazardous materials.
- Organizing a meeting with all relevant stakeholders (PI, CM staff, EH&S, research personnel) prior to the start of using hazardous materials.
- Providing laboratory personnel with knowledge of hazards to which they may be exposed and safety procedures to be followed including:
    - Being knowledgeable of good laboratory safety practice and a positive safety attitude.
    - Making available to the laboratory staff, copies of protocols that describe potential biohazards and the precautions to be taken. These protocols as well as biosafety concerns should be produced in the form of a standard operating procedure (SOP) for the work.
    - Providing laboratory staff with formal and informal instruction and training in the practices and techniques required to ensure safety.
    - Informing the laboratory staff of the reasons and provisions for any precautionary medical practices (e.g., medical examinations, serum collection, vaccinations, etc.)
    - Supervising the performance of staff to ensure that required safety practices and techniques are employed.
    - Making available to the laboratory staff, copies of the emergency plans covering accidental spills and personnel contamination resulting from hazardous research.

The IACUC will be responsible for:

- Paying particular attention to the animal use protocols proposing the use of potentially hazardous materials, including radioactive substances, infectious microorganisms and hazardous chemicals. These substances have the potential to cause harm to animals as well as those caring for and working with the animals.
- Providing oversight for all animal procedures conducted with the use of hazardous materials.

The Research Integrity Office will be responsible for:

- Administrative support of the IACUC members to facilitate their regulatory function.
- Maintaining policy and assure regular review and update as necessary by the IACUC.
- Providing assistance with the identification of hazardous materials during the IACUC protocol pre-review process and ensuring PIs and researchers work with EH&S.

The Office of Comparative Medicine (CM) will be responsible for:

- CM personnel will abide by this policy when performing tasks that may involve the use of hazardous materials.
- Veterinary Review of IACUC protocols providing advice to the PIs and researchers when the use of hazardous materials is proposed in an IACUC protocol or amendment.

The Office of Environmental Health and Safety (EH&S) will be responsible for:

- Oversight of hazardous materials storage, handling, disposal, and usage at FAU.
- Assisting researchers with development of safety protocols describing the use of hazardous materials in research animals.
- Assisting the IACUC with reviews of animal care and use protocols proposing the use of hazardous materials.
- Supporting the committee(s) reviewing hazardous materials use.

VII. Specific Hazards and Procedures

All lab personnel must complete a risk assessment form and the PI needs to inform CM staff when hazardous agents will be used. When hazardous agents will be used, a meeting between the stakeholders such as EH&S, CM staff and research personnel will take place for everyone to be informed of the risks and procedures to be followed. Cage cards will be utilized for flagging cages that are hazardous.

1. Use of Animal and Human Cells/Tissues

A. All proposed use of biological materials in animal models must be described in the animal use protocol form.
B. The PI is responsible for contacting the Attending Veterinarian or designee prior to using biological materials in research animals.
C. Appropriate testing methods regarding the safety of these materials will be determined based on consultation with the veterinarian.

2. Use of Radioactive Materials and Radiation Sources

A. Review of any animal research protocol involving the use of specified radioactive materials (including any naturally occurring or accelerator-produced radioactive material) and X-ray procedures must be coordinated between the Radiation Safety Committee and the IACUC.
B. It is the Principal Investigator's responsibility to submit the appropriate forms for review to the Radiation Safety Committee as well as to complete the appropriate section in the animal use protocol form.
C. The PI must attach final approval from the Radiation Safety Committee to the IACUC form. Final approval of the animal use protocol is dependent on receipt of Radiation Safety Committee approval.

3. Use of Infectious agents, viral vectors, recombinant DNA or Synthetic Nucleic Acids, Bacteria or Biological Toxins (Biological Hazards)

A. Review of any animal research protocol proposing the use of biological hazards such as Recombinant DNA, infectious agents, toxins of biological origins and human or non-human primate origin must be coordinated between the Institutional Biosafety Committee and the IACUC.
B. It is the Principal Investigator's responsibility to submit the appropriate forms for review to the Institutional Biosafety Committee as well as to complete the appropriate section in the animal use protocol form.

C. The PI must submit final approval from the Institutional Biosafety Committee to the IACUC. Final approval of the animal use protocol is dependent on receipt of Institutional Biosafety Committee approval.
D. Animal Biosafety Level (ABSL 2 studies require special housing and laboratory (procedure) space. A safety protocol must be developed between the PI, the BSO and the CM Director or Facility Manager. An inspection of the ABSL 2 housing area/ laboratory space may be required prior to the initiation of biohazard work.
E. Animals exposed to the hazards listed above must be handled with assigned safety precautions, even if they are transported to areas outside the primary containment room.
F. Final disposition of the animals exposed to hazards listed above must be described in the animal use protocol form.

4. Hazardous Chemicals

A. Review of any animal research protocol involving the use of hazardous chemicals must be coordinated between the EH&S and the IACUC.
B. It is the Principal Investigator's responsibility to submit the appropriate forms for review to the EH&S as well as to complete the appropriate section in the animal use protocol form.
C. Hazardous Chemicals must be stored and handled in accordance with the guidelines established by EH&S.

5. Other drugs with Unknown Hazards

A. Research studies may require the use of new and experimental compounds for which exact safety data is not available. For the safety of the research animals as well as humans, all compounds with unknown toxicological data must be treated as potentially hazardous.
B. Unknown chemicals should be mixed in a fume hood and only the amounts needed for dosing should be brought to the animal facility.
C. Unknown Chemicals must be stored and handled in accordance with the guidelines established by EH&S Committee.

6. Hazardous Waste

A. Animal wastes contaminated with radioactive materials, infectious agents or hazardous chemicals must be carefully managed to avoid human exposure or release to the environment.
B. Hazardous waste material must be conducted in accordance with the guidelines established by the Radiation Safety, the Institutional Biosafety Committee and EH&S Committee.

7. Occupational Health and Safety

Florida Atlantic University has an established Occupational Health and Safety Program for animal researchers to ensure the protection of those working and caring for animals. Any individual involved with animals must enroll in this program and update their information annually. Each lab member must complete a risk assessment form as part of the enrollment process.

VIII. Policy Renewal Date

9/24/2024

IX. References

1. The Guide for the Care and Use of Laboratory Animals, 8th edition
2. The IACUC handbook, 3rd edition
3. Animal Research Health and Safety Plan
4. Biological Safety Manual
5. Biological Waste Program
6. Bloodborne Pathogen Exposure Control Plan
7. Chemical Hygiene Plan
8. Laboratory Safety Manual
9. Hazardous Chemical Waste Disposal Policy
10. DOT Hazardous Materials Security Plan
11. Hazard Communication Program
12. HazMat Manual
13. Radiation Safety Manual for Lasers
14. Radiation Safety Manual

POLICY APPROVAL

Initiating Authority

Signature:_____ Date:_____

Name: Daniel C. Flynn, Ph.D., Vice President for Research

Executed signature pages are available in the Initiating Authority Office(s)