

Policy 2202
Institutional Care and Use of Laboratory Animals

Date of Current Revision: June 2022

Responsible Officer: Provost and Senior Vice President for Academic Affairs

1. PURPOSE

This policy provides the university community with procedures for the appropriate care and use of laboratory animals at the university.

2. AUTHORITY

The Board of Visitors has been authorized by the Commonwealth of Virginia to govern James Madison University. See Code of Virginia section 23-164.6; 23-9.2:3. The board has delegated the authority to manage the university to the president.

STATE OR FEDERAL STATUTE AND/OR REGULATION

In compliance with the Public Health Service (PHS) policy, "The chief executive officer shall appoint an Institutional Animal Care and Use Committee, qualified through the experience and expertise of its members to oversee the institution's animal program, facilities and procedures."

3. DEFINITIONS

Animal

Any live, vertebrate animal (e.g., traditional laboratory animals, wildlife, and aquatic species) used or intended for use in research, training (teaching), experimentation, or biological testing, or for related purposes.

Animal and Plant Health Inspection Service (APHIS)

The Agency within the United States Department of Agriculture responsible for administering the Animal Welfare Act.

Animal Facility or Vivarium

Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities used for animal housing, transport, maintenance, breeding, or experimentation, to include surgical manipulation. A satellite facility is any location outside the core facility where animals are housed for more than 24 hours.

Animal Use

The proper care, use, and humane treatment of laboratory animals produced for or used in research, testing, or teaching.

Animal Welfare Act

Public Law 89-544, 1966, as amended, (P.L. 91-579, P.L. 94-279 and P.L. 99-198) 7 U.S.C. 2131 et. seq. Implementing regulations are published in the APHIS 41-35-076 and are administered by the U.S. Department of Agriculture.

Animal Welfare Assurance or Assurance

Documentation from the Office of Laboratory Welfare that JMU complies with the Public Health Service policies.

Attending Veterinarian

The veterinarian responsible for the health and well-being of all laboratory animals used at the institution. A Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program authority and responsibility for activities involving animals at the institution.

Guide

Guide for the Care and Use of Laboratory Animals: Eighth Edition, National Academies Press, 2011, Washington, D.C., or succeeding revised editions.

Humane Care

Those actions taken to ensure that laboratory animals are treated according to the highest ethical and scientific standards.

Institutional Animal Care and Use Committee (IACUC)

An institutional committee appointed by the University president or his designee with responsibility to oversee the animal care and use program. The IACUC is responsible for all aspects of the animal care and use program in accordance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals and the *Guide for the Care and Use of Laboratory Animals*.

Institution

Any public or private organization, business, or agency (including components of Federal, state, and local governments).

Institutional Official

The University president or designee who has the authority to commit resources to the animal care and use program and ensure the requirements of the PHS Policy are met.

Office of Laboratory Animal Welfare (OLAW)

In accordance with the Health Research Extension Act of 1985 (P.L. 99-158) the division of the National Institutes of Health (NIH) responsible for providing guidance and interpretation of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, supporting educational programs, and monitoring compliance with the Policy by Assured institutions and PHS funding components to ensure the humane care and use of animals in PHS-supported research, testing, and training.

Principal Investigator

The individual with primary responsibility for a project, including designing, writing and implementing research, teaching, or testing activities involving live, vertebrate animals. PI qualifications require faculty status.

Protocol

A written description of the proposed procedures or activities involving live vertebrate animals.

Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals

Requires institutions to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, training, and biological testing activities conducted or supported by the PHS.

Quorum

A majority of the members of the Institutional Animal Care and Use Committee (IACUC).

Standard Operating Procedures (SOPs)

A list of procedures that govern the operation of an animal care facility on campus to assure the health and welfare of all animals used in research, teaching or both.

4. APPLICABILITY

According to the Assurance of Compliance with PHS Policy on the Humane Care and Use of Laboratory Animals, it is the responsibility of the university to provide direction and oversight for the care and use of live vertebrate animals in the conduct of scholarly research or other academic activities. The policy applies to all student and faculty research and teaching regardless of funding.

5. POLICY

It is university policy that the care, housing, use and procurement of animals should conform to the National Research Council *Guide for the Care and Use of Laboratory Animals* or succeeding editions and other relevant federal policies and procedures.

6. PROCEDURES**6.1 Institutional Animal Care and Use Committee or IACUC**

Membership or Composition – Described in the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals and the U.S. Department of Agriculture (USDA) Animal Welfare Act § 2143 b1 Research facility Committee; establishment, membership, functions, etc.

The IACUC will consist of at least 5 members and include:

- a. The Attending Veterinarian with training or experience in laboratory animal science and medicine, who has direct or delegated authority and responsibility for activities involving animals at the institution
- b. One member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy)
- c. One practicing scientist experienced in research with animals

- d. One member who is not affiliated with the university other than as a member of the IACUC
- e. IACUC Chairperson

6.2 Categories of Animal Use Subject to Review

The IACUC reviews all classroom (teaching) and research projects involving the use of living non-human vertebrate animals to ensure the humane care and use of animals including, but not limited to the following:

- a. Classroom exercises, demonstrations and lab projects
- b. Faculty or staff research projects
- c. Graduate student projects
- d. Undergraduate student honor projects
- e. University-approved research by investigators not affiliated with the university who propose to involve university students, staff or faculty members as part of a proposed research project

6.3 Criteria Used for Review of Proposals

The JMU IACUC in its review of proposed animal use protocols will determine that the proposed activity meets the following requirements as spelled out in JMU's Institutional Assurance to the U.S. Public Health Service Office of Laboratory Animal Welfare:

- a. Procedures involving animals must be designed and performed with due consideration of their relevance to human or animal physical or mental health, the advancement of knowledge, or the good of society.
- b. Animals selected for a procedure must be of an appropriate species and quality, and the number of animals used must be the minimum required to obtain valid results. Alternate approaches such as mathematical models, computer simulation and *in vitro* biological systems should be considered whenever possible.
- c. Consistent with sound research design, procedures with animals must avoid or minimize discomfort, distress and pain to the animals.
- d. Procedures that may cause more than momentary or slight pain or distress to the animals must be performed with appropriate analgesia, anesthesia or sedation; animals to undergo surgery or other painful procedures must always be properly anesthetized. Any variation from this requirement must be justified for scientific reasons in writing and must be reviewed and approved by the IACUC.
- e. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved must be painlessly sacrificed at the end of the procedure or, if appropriate, during the procedure.

- f. Multiple major surgical procedures on the same animal are discouraged and may be justified only when the procedures are related components of a research protocol. Such multiple surgical procedures require written justification and IACUC approval; approval will not be granted on the basis of cost savings alone.
- g. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding and non-medical care of animals will be directed by a scientist trained and experienced in the proper care, handling and use of the species being maintained or studied.
- h. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
- i. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
- j. All animals must be held in IACUC-inspected and -approved facilities. Surgical procedures must be performed only in facilities that have been approved by the IACUC for that purpose.
- k. Laboratory animals are not allowed outside the approved laboratory facility for more than 12 hours.
- l. Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association Panel on Euthanasia. Any variation from this requirement must be justified for scientific reasons in writing and must be reviewed and approved by the IACUC.

6.3.1 Designated Member Review (DMR)

DMR may occur only after all IACUC members have been provided with a list of the protocols to be reviewed and have an opportunity to call for Full Committee Review (FCR). If FCR is not requested, at least one member of the IACUC qualified to conduct the review is designated by the Chair. DMR may result in approval, require modifications in (to secure approval), or request FCR. DMR may not result in disapproval.

6.3.2 Full Committee Review (FCR)

FCR may only be conducted at a convened meeting with a quorum (simple majority) of members present. A majority vote of the quorum present is needed to approve, require modifications in (to secure approval), or withhold approval of a protocol. When substantive modifications are required in a protocol to secure approval, the resubmitted protocol must be reviewed using either FCR or DMR.

6.4 Procedures for Submitting Proposed Animal Use Protocols to the IACUC

A researcher must submit a protocol to the IACUC prior to the initiation of the research or teaching project. The electronic submission procedure and training manuals can be found on the ORI [Website](#).

Post-Approval IACUC Procedures:

- a. Protocol approval will be valid for a maximum of three years.
- b. The principal investigator will be contacted through the electronic Research Administration (eRA) online management system annually to verify the status of the project.
- c. If no significant change in the protocol has occurred, approval may be extended for a year.
- d. Amendments will be filed for minor and significant changes during the approval year.
 1. Examples of what is considered minor amendments can be found on the ORI website at the following:
https://www.jmu.edu/researchintegrity/iacuc/guidelines/Guidance_on_Amendments.pdf.
 2. Examples of what is considered significant amendments can be found on the ORI website at the following:
https://www.jmu.edu/researchintegrity/iacuc/guidelines/Guidance_on_Amendments.pdf.
- e. Minor amendments are processed through the IACUC office as administrative changes or through Designated Member Review (DMR).
- f. A significant change in the protocol may require a new application and approval.
- g. Approval will be canceled for discontinued projects.
- h. Significant departure from the original protocol requires prior approval from the IACUC.
- i. If the principal investigator fails to complete and return the Continuing Review form on time, the protocol will either be placed on a Holding Protocol by the IACUC, effective on the one-year anniversary of the Protocol's initial approval or most recent Continuing Review form approval, and no further activities can be undertaken with animals until the IACUC approves continued activity on the protocol. If a review cannot be conducted or continued activity cannot be approved before the end of the Administrative Hold period, the Protocol will be closed.

6.5 Statement of Concern/Complaint Concerns about animal abuse or infractions of animal care and user regulations:

Anyone with a concern or question about animal care and use at James Madison University, including protocol noncompliance or animal treatment, is expected to contact the IACUC Chair, Attending Veterinarian, Vivarium and Lab Safety Manager, or Director/Assistant Director of Research Integrity. The IACUC website has a link to "[Reporting Concerns](#)" regarding animal use or improper handling/care of animals. The link provides faculty/staff/students with contact information to make a report or to discuss a perceived problem. The IACUC website also has a "[Report Concern Form](#)" where anyone at JMU can

anonymously report concerns. The JMU Whistleblower Policy, with contact phone numbers, is also posted in prominent locations in all animal facilities. The Attending Veterinarian, Animal Lab staff and individual IACUC members must also report any suspected incidence of noncompliance. Reports made through the ORI are delivered to the IACUC Chair for action. Strict confidentiality regarding the identity of the individual reporting the animal welfare concern will be maintained to the extent possible and allowable by law.

The IACUC chair will appoint a subcommittee to investigate the concern. The findings of this investigation will be presented at a fully convened IACUC meeting. The Committee will then decide on a remediation strategy for the concern. A report of the concern will be forwarded to the IO. No committee member, facility employee, laboratory personnel or student shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standard in accordance with [University Policy 2205, Research and Scholarship Misconduct](#).

- 6.6. All animal care facilities (vivaria) will follow the SOPs that apply to their particular species. These SOPs are posted on the IACUC website at:
<http://www.jmu.edu/researchintegrity/iacuc/index.shtml>.

7. RESPONSIBILITIES

- 7.1 The IACUC is responsible for oversight of the animal care and use program and its components as described in the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), Animal Welfare Act (AWA), and the *Guide for the Care and Use of Laboratory Animals* (Guide). It reviews research protocols proposing the use of vertebrate animals to ensure that the described care and use of animals are in compliance with federal rules and regulations and university policy. The IACUC is responsible for the following:
- a. Reviewing the institution's program for the humane care and use of animals at least once every six months using the Guide as a basis for evaluation.
 - b. Inspecting all of the institution's animal facilities at least once every six months (including satellite facilities) using the Guide as a basis for evaluation.
 - c. Preparing reports of IACUC evaluations as set forth in the PHS policy and/or AWA and submitting the reports to the Institutional Official.
 - d. Reviewing concerns involving the care and use of animals at the institution.
 - e. Making written recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training.
 - f. Reviewing and approving, required modifications (to secure approval or withhold approval) of those activities related to the care and use of animals as set forth in the PHS policy and/or AWA.
 - g. Notifying investigators, in writing, of its decision to approve or withhold approval of those activities related to the care and use of animals or of modifications required to secure IACUC approval as set forth in the PHS policy and/or AWA.

- h. Authorizing the suspension of an activity involving animals as set forth in the PHS policy and/or AWA.
- i. Ensuring lawful procurement of vertebrate animals.
- j. Reviewing and approving all new, continuing, or revised protocols involving use of animals in university-supported and/or externally funded research or instructional activities.
- k. Reviewing any significant amendments to a protocol.
- l. Overseeing adherence to the SOPs.
- m. Conducting post-approval monitoring of ongoing research activities to ensure compliance with approved protocols.

7.2 The principal investigator is responsible for the following:

- a. Submitting a properly executed protocol for each project to the Office of Research Integrity, the administrative arm for IACUC. The protocol will be distributed for review and approval to the IACUC. No work may commence until IACUC approval has been obtained.
- b. Ensuring that all animals are obtained lawfully.
- c. Ensuring that arrangements are made for obtaining any special permits necessary for the acquisition of certain exotic, wild and restricted species.
- d. Ensuring that personnel are adequately trained in the care, handling, and restraining of all animals used in relevant procedures.
- e. Establishing proper procedures in their laboratory or study area for all aspects of animal care and use such as anesthesia, postoperative care, preoperative care, sampling techniques and euthanasia, as well as disposing of animal carcasses and waste. The principal investigator or instructor is not responsible for the physical removal of animal carcasses and waste. However, the principal investigator is responsible for implementing procedures for preparation of wastes according to the *Guide* for collection and disposal. Waste disposal will be collected and disposed of in a safe and sanitary manner under the auspices of the Environmental Health Coordinator.
- f. Ensuring that instructions to laboratory personnel are implemented and documented, including the occupational health and safety program.
- g. Ensuring that aseptic surgery is performed in a facility designed in accordance with the recommendations in the *Guide for the Care and Use of Laboratory Animals* 2011 or succeeding editions.
- h. Ensuring that procedures are in compliance with all campus policies, including regulations concerning the use of agents such as radionuclides, biohazardous agents, etc., as well as those involving the use of vertebrate animals. Experimentation with such

agents may require registration with, or approval by, other campus committees or offices.

All departments, offices and employees that generate, receive, or maintain public records under the terms of this policy are also responsible for compliance with Policy [1109](#) – Records Management.

8. SANCTIONS

Sanctions will be commensurate with the severity and/or frequency of the offense and may include termination of employment.

9. EXCLUSIONS

None.

10. INTERPRETATION

The authority to interpret this policy rests with the president and is generally delegated to the Director of ORI and the IACUC Chair.

Previous Version: February 2013

Approved by the President: November 2002