

# MONMOUTH UNIVERSITY

## Policies and Procedures

**Policy Name:** Humane Care and Use of Vertebrate Laboratory Animals

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**Approved By:** President's Cabinet      **Issued By:** Thomas Pearson, Vice  
President for Academic  
Affairs/Provost

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### I. PURPOSE

- A. Monmouth University is committed to the humane care and use of animals in activities related to research, testing and teaching. The University has adopted on an institution-wide basis the principles regarding animal care as stated in the Animal Welfare Act and the Guide for the Care and Use of Laboratory Animals ("Guide") and is guided by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training.
- B. This policy applies to all aspects of non-human vertebrate animal care and use by University personnel including review of animal welfare considerations of all research and teaching protocols and semiannual facility and program review; procurement, transportation and housing of laboratory animals; the appropriate use of anesthetics, analgesics, and tranquilizers; the use of aseptic technique, multiple survival surgery; the consideration of alternative (adjunct) methodology; unnecessary duplication of research; training of research and animal care staff; veterinary care; and occupational health. All investigators using animals in research, testing, and teaching must comply with all Monmouth University Animal Care and Use Policies.
- C. This policy delineates the responsibilities of the University and the Institutional Animal Care and Use Committee (IACUC) for the protection of vertebrate animals and the Research Investigator and sets forth the type of review research projects must receive from the IACUC.
- D. This policy contemplates that research that meets the requirements of this policy shall be approved and not rejected for reasons that fall outside the purview of this policy. The IACUC shall not consider general policy or political reasons as a basis for making its decisions.

## II. COMPLIANCE WITH APPLICABLE LAWS

In accordance with Monmouth University policy governing the use of vertebrate animals in research, all vertebrate animal research under the aegis of Monmouth University will be performed in accordance with the following authorities. In addition, Monmouth University will also adhere to all other applicable federal, state and local laws and regulations.

### A. United States Department of Agriculture (USDA)

The staff of the Regulatory Enforcement and Animal Care (REAC) branch of the Animal and Plant Health Inspection Service (APHIS) division of the USDA is responsible for enforcing the regulations and standards promulgated by the Secretary of Agriculture under the mandate of the Animal Welfare Act (AWA). The regulations define the institutional responsibility for assuring compliance with the AWA. The standards set minimal requirements for humane handling, housing, feeding and watering, sanitation, exercise for dogs, psychological well being of primates and transportation. Compliance requirements include periodic unannounced inspections by REAC personnel and an annual report containing institutional assurances of acceptable standards for animal care and use, including summaries of any exceptions granted for scientific necessity, and documentation of the animals used.

### B. Public Health Service (PHS)

The Office of Laboratory and Animal Welfare (OLAW) is responsible for the general administration and coordination of NIH policy regarding animal care and use. Public Health Service awarding units may not make an award for a project involving animals unless the institution submitting the application or proposal is on the list of institutions that have an acceptable animal welfare assurance letter on file with OLAW and the responsible institutional official has provide verification of approval by the IACUC. All records that directly relate to applications, proposals and proposed changes in ongoing research reviewed and approved by the IACUC must be maintained for at least three years after completion of the research and must be accessible to the OLAW with reasonable notice.

## III. THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

- ### A. The Institutional Animal Care and Use Committee (“IACUC”) is designed to assist researchers and institutional administrators with their duty to protect the rights and welfare of vertebrate animals in accordance with this policy.

B. The IACUC shall:

1. review at least once every six months the institution's program for humane care and use of vertebrate animals, using the Guide as a basis for evaluation.
2. inspect at least once every six months all of the institution's animal facilities (including satellite facilities) using the Guide as a basis for evaluation;
3. prepare reports, including any minority views, of the IACUC evaluations conducted as required by (B) (1) and (B) (2) above. These reports shall be reviewed and signed by a majority of IACUC members before being submitted to the Provost and Faculty Council. The reports shall be maintained by the institution and made available to the Animal and Plant Health Inspection Service (APHIS) and to officials of sponsoring Federal agencies upon request. The reports must contain a description of the nature and extent of the institution's adherence to the Guide and Public Health Service (PHS) policy, identify specifically any departures from provision of the Guide and PHS policy, and state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which is inconsistent with PHS policy and, in the judgment of the IACUC, is (or may be) a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency. Significant deficiencies not corrected as scheduled shall be reported in writing within 15 business days to APHIS and to any Federal sponsoring agency. The IACUC may, at its discretion, determine the best means for conducting an evaluation of the institution's programs and facilities. While the IACUC may invite ad hoc consultants to assist in conducting the evaluation, the IACUC remains responsible for the evaluation and report;
4. review concerns involving the care and use of animals at the institution;
5. make recommendations to the Provost regarding any aspect of the institution's animal program, facilities, or personnel training;
6. develop and administer an Animal Use Protocol Application for review and approval of proposed activities using vertebrate animals;

7. review and approve, require modifications to (to secure approval), or withhold approval of (i) those components of proposed activities related to the care and use of animals as specified in PHS Policy, or (ii) proposed significant changes regarding the use of animals in ongoing activities;
  8. suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or PHS Policy; and
  9. notify principal investigators in writing of its decision to approve, require modifications to, or withhold approval (with justification for its decisions) of those activities related to the care and use of animals. The principal investigators shall be given an opportunity to respond in writing (and in person if requested) to disapproved activities. The IACUC may reconsider its decision in light of information provided by the investigator.
- C. The IACUC shall consist of the following members:
1. three tenured full-time faculty members from the University who shall be chosen by the University's Faculty Council. The faculty members shall be practicing scientists experienced in research involving animals. Faculty serving on the IACUC shall be paid a stipend for their services as determined by the Provost.
  2. a Doctor of Veterinary Medicine who is certified or has training or expertise in laboratory animal science and medicine.
  3. a member of the University's administration, chosen by the Provost, whose primary concerns are in a non-scientific area.
  4. a member of the surrounding community, chosen by the Provost, who is not affiliated with the University.
- D. Both the Provost and the Faculty Council shall be guided by the requirements of federal regulations, the Guide and other applicable requirements, in making the selections for individuals to serve as members of the IACUC. Preference should be given to the selection of tenured faculty appointees if available.
- E. Individuals serving on the IACUC shall serve for a term of three (3) years and shall not serve more than two (2) consecutive terms with the exception

of the Doctor of Veterinary Medicine who shall serve as an ex officio member of the IACUC. The two-term limit may be waived if eligible faculty are not available. Each yearly period of a term shall commence at the beginning of the academic year (first day of classes in the fall semester) and shall conclude the day before the first day of classes of the next succeeding academic year. The initial appointment to the IACUC shall be made within thirty (30) days of the final approval of this policy by the University's faculty. The first year of the appointment of the initial members of the IACUC shall conclude on the day before the start of classes for the Fall 2004 semester. In order to provide for the staggering of terms for members of the IACUC, the initial appointments shall be for the following lengths of time:

1. one faculty member for two (2) years
2. two faculty members for three (3) years
3. member of the surrounding community for two (2) years
4. administration member for three (3) years

- F. At its first meeting, the IACUC shall choose a chairperson by a majority vote of its members. The chair shall serve for such term as determined by the IACUC but shall in no event serve for more than three (3) consecutive years.
- G. The Provost shall appoint sufficient staff to assist the IACUC in the fulfillment of its duties and responsibilities. The IACUC staff shall be responsible for ensuring that the IACUC is properly supported for its meetings and other activities and shall report to the Provost through the Chair of the IACUC.
- H. The IACUC shall meet at least once each month to conduct its business. The IACUC Chair may cancel any monthly meeting of the IACUC if it has no business for its consideration for any particular monthly meeting. Any determinations made by the IACUC at its meetings shall be communicated to affected parties within two business days of the meeting. All decisions will be by majority vote of the committee members present and no member may be present during review of a proposal initiated by that member, unless specifically requested by the committee.

#### IV. **REVIEW OF RESEARCH**

- A. All research and other laboratory activities involving vertebrate animals must be reviewed and approved prior to commencing such activities.

- B. The requirements of this section apply to any research project conducted at the University or elsewhere, by anyone affiliated with Monmouth University (i.e. all faculty, staff, undergraduate, and graduate students).
- C. Any researcher, faculty or student that plans to conduct research projects involving vertebrate animals must complete an IACUC Animal Use Protocol Application.

V. **PROJECT INVESTIGATOR RESPONSIBILITIES**

- A. The individual responsible for the conduct of the activity, i.e., the responsible project investigator, has primary responsibility for the humane use of vertebrate animals used in research and teaching. Specifically, the investigator is responsible for:
  - 1. Carefully designing procedures involving animals,
  - 2. Adhering to ethical codes and applicable policies and procedures of the University, the sponsoring agency, relevant professional organizations and cooperating institutions, if any,
  - 3. Ensuring that all subordinate personnel have received appropriate training and instruction in the humane care and use of animals before subordinate individuals are involved in animal use.
  - 4. Ensuring that all subordinate personnel are appropriately involved in the occupational health program before subordinate individuals are involved in animal use.
  - 5. Preparing animal use protocols that must be approved by the IACUC prior to commencement of the activity. Proposed changes in animal protocols, i.e., those that directly affect the animals, shall be submitted to the IACUC for approval prior to commencement of the changes.
  - 6. Reporting promptly to the IACUC any unanticipated problems involving risks to participants or others,
  - 7. Retaining required records.
- B. Animal care and use shall be conducted with due consideration for the health and comfort of the animals and in conformance with all applicable laws and regulations, including those pertaining to occupational health and environmental health and safety.

- C. Research, testing or teaching involving animals shall be conducted using, methods that are appropriate for the study. Where relevant, these methods include accepted surgical techniques, aseptic procedure, preoperative and postoperative and pre-procedural and post-procedural care, use of pain relieving medications, approved methods of euthanasia, and verification of animal death prior to disposal.
- D. Research, testing and teaching procedures shall be designed to avoid discomfort, distress and pain. Pain and distress shall be relieved by the appropriate use of anesthetics, analgesics or other procedures throughout the experiment except when it has been specifically determined that the use of such drugs or procedures would defeat the purpose of the experiment and there is no available alternative.
- E. The investigator in charge of the research project or teaching activity, or a qualified designee, shall monitor its progress to identify any unanticipated effects on the animals, to implement any modifications necessary to avoid pain or relieve distress and to reevaluate the desirability of continuing the study if there is reason to believe its continuation may result in unnecessary injury or discomfort to the animals.

VI. **ACADEMIC DEPARTMENT CHAIR/DESIGNEE RESPONSIBILITIES**

- A. The chair of each academic department, or his/her designee, is responsible for:
  - 1. Ensuring that faculty, staff, and students are kept informed of the University and departmental policies and procedures and of their responsibilities for complying with this policy.
  - 2. Reporting promptly in writing to the IACUC any unanticipated problems involving vertebrate animal research at the University.
  - 3. Ensuring that animals are purchased/obtained only from an appropriate source and that IACUC approval has been obtained prior to purchase.

VII. **PROTOCOL REVIEW PROCESS**

- A. All animal care and use protocols will be prepared according to the IACUC-approved format and submitted to the IACUC Office. The protocols are assigned file numbers according to the semester and year. The proposed research protocols and meeting agenda are distributed to the IACUC members prior to review at the subsequent meeting. Before a

protocol can be approved, consultation with the Doctor of Veterinary Medicine is required for all proposals involving the use of animals.

- B. There are three types of Committee review: full, expedited or executive. Determination of the type of review is usually based upon the expected level of animal pain or discomfort and types of procedures.
- C. The following steps are involved in the review process:

**Step 1: *Submission of the Protocol.*** Investigators submit completed Protocols to the IACUC Office in hard copy or as otherwise instructed by the IACUC.

**Step 2: *Initial Review.*** Following the receipt of a Protocol by the IACUC Office, the type of review a proposal will receive (executive, expedited or full committee) based on the expected level of animal discomfort and types of procedures will be verified. Completeness of the protocol is also checked at this time.

**Step 3: *Review (By Type)*** At monthly meetings, the IACUC considers new protocols requiring full committee review, the reports of expedited reviews and reports of executive reviews. Possible outcomes of the Committee's review include unqualified approval, approval pending modification(s) and/or clarification(s), table (deferral), or disapproval. Actions require majority vote of the committee members present. No committee member may vote on a proposal initiated by that committee member.

- a. **FULL REVIEWS** – Two reviewers are assigned. The primary reviewer is always a scientific representative of the committee and is responsible for presenting a summary of the protocol at the meeting along with my concerns or points requiring clarification. The secondary reviewer adds any additional concerns. The protocol is then open for discussion by the Committee, which includes the Doctor of Veterinary Medicine.
- b. **EXPEDITED REVIEW** – One reviewer is assigned. The reviewer is given 7 days to complete the review and return to the IACUC office. The reviewer's comments and the protocol are then forwarded to the remainder of the Committee for their review. If no further comments are received and there is no request for a full committee review, a letter requesting clarifications and/or modifications is sent to the investigator or,



if a recommendation to approve outright has been made, a verification of approval is sent.

- c. **EXECUTIVE REVIEW** – The chair alone (or his designee from the Committee) reviews and approves protocols falling in this category. This category includes continuing reviews, previously approved protocols that have been resubmitted or identical protocols submitted to different funding agencies, protocols with no direct animal use, e.g. funds will be used for salary support only (on a previously approved protocol), or use of shared animal products or slaughterhouse materials.

**Step 4: Investigator Notification.** If a protocol receives unqualified approval, the investigator is provided with a verification of approval (including a protocol approval number) and letter certifying the approval. In cases where the IACUC requires clarification(s) or modification(s), the investigator is notified by the IACUC Chair in a letter. In such cases, the approval is issued following receipt of an acceptable response from the investigator. In cases of a tabled or disapproved protocol, the investigator is notified by the Chair and advised as to available options.

## VIII. **CRITERIA FOR REVIEW**

- A. All proposed activities are reviewed to ensure that the following federal requirements for granting IACUC approval are met:
  1. **Activities** – All activities involving animals must be in accord with USDA Regulations/PHS policy.
  2. **Pain/Distress** – Must avoid/minimize discomfort/distress/pain. If pain/distress is caused, appropriate sedation, analgesia or anesthesia will be used. Attending veterinarian must be involved in planning. Use of paralytics is prohibited. Animals with chronic/severe unrelievable pain will be euthanized painlessly.
  3. **Alternatives** – The PI has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animal and has provided a written narrative description of the methods and sources, e.g., the Animal Welfare Information Center, used to determine that alternatives were not available.
  4. **Rationale and Methods** – all proposals must include:

- a. Identification of the species and the approximate number of animals to be used.
  - b. A rationale for involving animals and for the appropriateness of the species and numbers of animals to be used.
  - c. A complete description of the proposed use of the animals;
  - d. A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals; and
  - e. A description of any euthanasia method to be used.
5. **Duplication** -- Must provide assurance that activities do not unnecessarily duplicate previous efforts.
  6. **Surgery** – Must meet requirements for sterile surgery and pre/post operative care. Cannot use one animal for several major operative procedures from which it will recover, without meeting specified conditions.
  7. **Euthanasia** – Euthanasia method must be consistent with USDA Regulations/AVMA recommendations.
  8. **Housing/Health** – Animal living conditions must be consistent with standards of housing, feeding and care directed by veterinarian or scientist with appropriate expertise. Medical care must be provided by qualified veterinarian.
  9. **Qualifications** – Personnel must be appropriately trained and qualified.
  10. **Deviation from Requirements** – Must be justified for scientific reasons, in writing.
- B. The Committee’s review process always includes a check for compliance with all applicable IACUC or institutional policies and procedures.

IX. **STUDENT SUBMISSION OF PROTOCOLS**

Students submitting a research proposal must have a faculty member who certifies that the student is knowledgeable about the regulations and policies governing research with vertebrate animals and has sufficient training and experience to conduct the particular study. The faculty member must also agree to provide oversight regarding all aspects of animal care and use.

X. **CONTINUATION REVIEWS**

- A. Animal research protocols are approved for a three-year term, subject to continuing review at least annually.
- B. A letter shall be sent two months prior to the anniversary date of the last review to the principal investigator indicating that the continuing review is due. The investigator must complete and return a Continuing Review Summary, which is then subjected to Executive Review by the IACUC. Upon recommendation of the reviewer, the protocol is either approved outright for period of time up to an additional year or a protocol modification requested with subsequent Full or Expedited Review depending on the extent of the modification.
- C. At the end of the third year of a protocol, the investigator must resubmit it for Committee review in order to continue research activities. A new Animal Use Protocol Form must be submitted; this form undergoes the same review process as any new protocol. The renewal should include all previous modifications or amendments made to the protocol since its original approval.

XI. **MODIFICATIONS OR ADMENDMENTS TO APPROVED PROTOCOLS**

- A. Modifications to approved protocols must be documented appropriately, reviewed, and approved. The method for obtaining approval for a modification or amendment is similar to that for a complete Protocol. A letter requesting the modification including an explanation of the rationale for the change, and any amended Animal Use Protocol pages resulting from this change should be submitted to the IACUC.
- B. The IACUC Chair or designee, in consultation with the Doctor of Veterinary Medicine if necessary, determines if the change is “minor” or “significant”.

- C. Minor modifications may entail such things as small numbers of additional animal subjects, addition of new personnel, or perhaps changing the route of administration of drug. Minor modifications may be approved administratively by the IACUC Chair and the Doctor of Veterinary Medicine without full review.
- D. Significant modifications may entail a large change in numbers of animals being used or requested, an increase in invasiveness, a change in species, an increase in pain or discomfort, or a change in the method of euthanasia. Major modifications require review by the full committee.
- E. The Veterinarian will notify the IACUC of any changes in choice of anesthetics or analgesics and any changes in their dosage.

## XII. **RECORD RETENTION**

Federal regulations require that all records relating to the IACUC and to human participants' activities be retained for at least three years after completion of the research. Records, including collected data, must be accessible for inspection at any time and for copying by authorized representatives of the University or the agencies sponsoring the research.

## XIII. **INSTITUTIONAL OVERSIGHTS:**

- A. The University IACUC has the authority to suspend or terminate approval of any research conducted at or sponsored by the University that is not being conducted in accordance with the IACUC's requirements or that has been associated with unexpected serious harm to vertebrate animals. Any suspension or termination of approval will include a statement of the reasons for the IACUC's action and shall be reported promptly to the investigator, the appropriate institutional officials, and OLAW. For PHS supported work so terminated or suspended, Human Health and Services (HHS) regulations require that the Secretary of HHS be notified as well.
- B. Research that has been approved by the IACUC may be subject to further appropriate review and approval by officials of the University. University officials may not approve the research if it has been disapproved by the IACUC.

## XIV. **REPORTING OF ADVERSE EVENTS:**

The responsible project investigator must promptly notify the IACUC in writing of any problems that arise during the course of the research project. Upon receipt of such notification, the IACUC shall conduct a continuing review of the research project

pursuant to Section X of this policy. Problems include unanticipated side effects or adverse reactions from participation in the project.

XV. **INSTITUTIONAL EDUCATIONAL PROGRAM**

- A. The University IACUC shall develop educational programs for members of the University community engaged in vertebrate animal use or related issues in order to ensure that members of the University community are properly educated and aware of issues and requirements in this area.
- B. Such educational programs shall be designed for various constituencies of the campus community including the University IACUC and its staff, principal investigators, faculty and others.
- C. The University IACUC shall report annually to the Provost with regard to recommendations for the educational programs for the upcoming academic year including their frequency and the method of their delivery. Upon adoption of this policy by the University, the University IACUC shall provide the Provost with a recommendation of an immediate educational program within thirty (30) days of the commencement of their activities.

XVI. **TERMINATION OF IACUC PROTOCOLS**

It is the responsibility of the investigator to notify the IACUC when a project is completed. Projects that have been completed, withdrawn or terminated are closed immediately upon notification. All animal use on a specified protocol is stopped. No further purchase of animals can be made under the specified protocol number. All closed projects are filed with the IACUC for a 3-year period from date of closure.

XVII. **SEMIANNUAL REVIEW OF PROGRAM AND FACILITIES AND PROTOCOL FOLLOW UP**

Twice each year the IACUC shall conduct a complete review of the Monmouth University Animal Care and Use Program and inspect facilities where animals are housed and/or used. The NIH Guide for the Care and Use of Laboratory Animals and Animal Welfare Regulations are the principal documents used by the IACUC in its evaluations. Researchers who house animals in their laboratories over 12 hours should expect visits by the subcommittee of the IACUC at approximately 6-month intervals. In addition to looking at the research facilities during the semiannual inspection, IACUC members will conduct protocol follow-up visits at least annually. Members will meet with the investigators and their staff to discuss animal use procedures described in the applicable protocol(s), inspect drugs and materials intended for *in vivo* use, and inspect the research animal records.

XVIII. **GENERAL POLICIES**

- A. When procedures are likely to cause more than momentary or slight pain or distress, the Doctor of Veterinary Medicine should be consulted and procedures shall be performed with appropriate sedatives, analgesics or anesthetics unless withholding such agents is justified for scientific reasons and approved by the IACUC. Such procedures shall be closely supervised by the investigator in charge of the project.
- B. Methods used for euthanasia must be those recommended by the American Veterinary Medical Association Panel on Euthanasia or approved by the IACUC.
- C. Survival surgery shall be done in appropriate facilities using aseptic technique as described in the Guide for the Care and Use of Laboratory Animals. Multiple survival procedures may be permitted only with prior approval of the IACUC. Cost alone is not an adequate justification for performing more than one major survival surgical procedure on an animal.
- D. Procedures requiring prolonged restraint (greater than 12 hours) must be scientifically justified with assurances that a member of the veterinary staff examines the animal on a predetermined schedule to insure the animals well being.

XIX. **ANIMAL CARE AND HOUSING**

- A. Campus practices in the housing and care of animals shall conform to the Guide for the Care and Use of Laboratory Animals and the Public Health Service Policy on Humane Care and Use of Laboratory Animals.
- B. No satellite facility (defined as housing animals for greater than 24 hours) shall be developed or maintained without the approval of the IACUC. Animals removed to teaching or research laboratories must be returned to an accredited animal facility within 24 hours. Animals shall be transported in appropriate, clean containers with proper animal restraint to avoid injury.
- C. Any animal illness, injury, or anticipate abnormal behavior shall be reported promptly to the University Veterinarian.
- D. Disposal of animal carcasses shall be conducted in accordance with guidelines developed by the IACUC. Animals used for teaching or research are the property of Monmouth University. No animal shall be removed from or brought onto University property for the purpose of teaching or research without the approval of the IACUC.