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|  ROSS UNIVERSITY SCHOOL OF VETERINARY MEDICINE | General Policy on the Care and Use of Animals Pol.001 | Issued | September 2012 |
| | | Revised | November 2020 |
| | | Authority | IACUC |

1. Policy Statement

Ross University School of Veterinary Medicine (RUSVM) regards the use of animals in research, teaching, and testing to be an integral component of continued progress in science, education, and agriculture. The University expects all of its animal facilities and programs to maintain the highest standards of animal care and use, and to be operated in accordance with applicable local and U.S. federal laws, regulations, policies and guidelines. The Institutional Animal Care and Use Committee (IACUC), a standing committee at RUSVM, oversees and evaluates all aspects of the University's Animal Care and Use Program. The composition and responsibilities of the IACUC Committee are mandated by the Animal Welfare Act (Public Law 99-198).

Animal facilities, programs and student organizations will be operated in accordance with the following regulations and/or guidelines, with the most recent versions applicable:

- The U.S. Department of Agriculture (USDA) Animal Welfare Act (1966) and Animal Welfare Regulations (AWAR)
- Code of Federal Regulations – Title 9. Animals and Animal Products (2013) and policies
- U.S Department of Health and Human Services (HHS) Health Research Extension Act (1985)
- The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, 2015
- The Guide for the Care and Use of Laboratory Animals, Eight edition, National Research Council, 2011 (the *Guide*)
- The Guide for the Care and Use of Agricultural Animals in Research and Teaching, Federation of Animal Science Societies, Third edition, 2010 (the *Ag Guide*)
- other applicable local and U.S. federal laws, regulations, policies and guidelines
- AVMA Guidelines for Euthanasia (2013)
- In the event that a protocol is part of a collaboration with a European country, the European ETS 123 will also be followed
- Existing RUSVM IACUC reviewed and approved Policies, Guidelines and Standard Operating Procedures (SOPs)

The IACUC, appointed by the Institutional Official (IO), is qualified through the experience and expertise of its members to advise, monitor, inspect, and oversee the entire University Animal Care and Use Program, facilities and procedures and ensure that they meet the applicable regulations. When required, the IACUC utilizes consultants for specific protocol review or committee advice. The consultant may offer opinions and advice, but may not vote on any application or use.

The IACUC addresses concerns regarding the welfare of animals used and is expected to be the conscience for the University on animal welfare concerns. As a decision-making body, the IACUC ensures that all animals in experimental research, teaching and testing are used appropriately and are treated in accordance with the highest standards of humane care. Maintaining these standards also is an important part of the teaching mission of the University.

2. Purpose

This policy outlines the responsibilities of the IACUC and provides the basis for subject specific IACUC Policies, Guidelines and Standard Operating Procedures (SOPs). Through this policy, the IACUC is able to support the University's commitment to the highest ethical standards of animal care and use.

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3. Scope and Responsibilities

All units of the University are affected by this policy. The following persons should read this policy:

- All faculty, students, research and teaching personnel and staff members involved in the care and use of animals
- Heads of units where animals are used in research, teaching, or testing, and
- Institutional Animal Care and Use Committee members

This policy does not apply to the clinical care of client-owned animals, which is not a part of an IACUC approved protocol, at the RUSVM Veterinary Teaching Hospital. This policy can apply, at the discretion of the IO, to non-teaching and non-research animals owned by the university. This policy does apply to student organizations that have activities involving animals.

4. External Documentation / References / Definitions

See Appendix I and II.

5. IACUC Structure and Reporting

U.S. federal regulations require that the membership of the IACUC include, at a minimum:

- A veterinarian
- A scientist experienced in research involving animals
- A member whose principal expertise is in a nonscientific field of study
- An individual not affiliated with the University
- A chair of the committee.

The IACUC is mandated by the Health Research Extension Act (HREA) of 1985 and the AWA. The membership of the IACUC is defined in the IACUC by-laws.

The IACUC and the Attending Veterinarian (AV) reports to the Institutional Official (IO).

6. IACUC Responsibilities

6.1 Overview

IACUC responsibilities are mandated by U.S. federal law. Responsibilities of the IACUC include, but are not limited, to the following:

1. Review the components of the Animal Care and Use Program at least every six months, including the training program
2. Inspect the on campus animal facilities and animal study areas at least every six months
3. Prepare and submit reports on the inspections and make recommendations to the Institutional Official (IO) regarding any aspect of the Animal Care and Use Program, the research facilities or personnel training
4. Review and approve or withhold vertebrate animal research, teaching or testing activities (protocols) before they are initiated
5. Review and approve or withhold modifications to previously approved Animal Care and Use protocols
6. Conduct post approval monitoring (PAM)

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7. Investigate and suspend animal use in accordance with federal regulations
8. Review and investigate concerns involving animal care and use

6.2 Review of the Animal Care and Use Program

The IACUC is required to review the RUSVM Animal Care and Use Program at least once every six months using the applicable local and US laws, regulations, policies and guidelines, as well as RUSVM IACUC policies, Guidelines and SOPs as the basis for evaluation. The IACUC is responsible for keeping abreast of changes in animal use legislation and guidelines and recommending modifications to the University's program to ensure that research and the animal use program fully comply with the letter and the spirit of the law.

6.3 Training and Education

The IACUC is responsible for maintaining communication with the faculty, staff, students and appropriate Departmental Committees on the Use and Care of Animals program.

All personnel utilizing and/or handling animals for research, teaching, testing and husbandry care must be adequately trained, educated and qualified in the principles of laboratory animal science and lab safety, the specific procedures that they are expected to perform with the species of animals being used, their roles and responsibilities in ensuring the humane care and use of animals, and the ethical principles and University policies and procedures governing the use of animals in research, testing and teaching.

Training requirements for personnel involved in animal care and use are determined by the IACUC. The IACUC is responsible for ensuring ongoing compliance with those requirements.

The training requirements set by the IACUC are based on:

- 1) the procedures the individual will perform
- 2) the species that will be used
- 3) special considerations related to the role of the person in the animal care and use program.

All personnel working with animals must complete the assigned training before they can begin work with animals.

All IACUC members also must complete training to ensure their understanding of U.S. federal regulations, local regulations and University policies. All IACUC members will be required to attend at least two webinars per year. Attendance to webinars will be recorded by the IACUC Administrator.

6.4 Inspections

The IACUC is required to inspect, the University's animal facilities, including animal study areas, which are defined as any area in which animal work is performed, at least once every six months. Not only is the physical facility inspected, such as animal housing and facility maintenance, but the entire animal program is reviewed. This can involve reviewing animal health records, observing surgery, reviewing post-operative records, and reviewing the biosafety, chemical safety, radiation safety, and occupational health program, as well as all USDA inspections, AAALAC program reviews (if applicable) and assessments. Deficiencies, if noted, are documented and responses to those deficiencies reviewed by the IACUC in order to ensure compliance with all applicable laws, regulations, policies and guidelines as well as RUSVM IACUC Policies, Guidelines and SOPs.

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6.5 Reporting / Recommendations

Internal reporting:

The IACUC reports to the IO and all meeting minutes and reports are reviewed by the IO. The IACUC makes recommendations to the IO regarding any aspect of the University's Animal Care and Use Program, facilities or personnel training.

The IACUC makes a written report of its findings from reviews of the Animal Care and Use Program and facilities inspections. The report must be signed by a majority of IACUC committee members and must include any minority views, if these views are expressed during the program review and inspection. This report is submitted to the IO for review. The results of the IACUC inspections are transmitted to individual Facility Managers/Heads of Sections with recommendations or suggestions for improvement or corrections if noted, and time frames for response. Problem areas not resolved satisfactorily by this mechanism of communication are subsequently transmitted (with recommendations) to the IO for ultimate resolution.

External reporting:

Notice NOT-OD-05-034 of February 24, 2005 states that prompt reporting to the Office of Laboratory Animal Welfare (OLAW) under the PHS Policy on Humane Care and Use of Laboratory Animals (Policy), section IV.F.3 requires that the IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:

- a) any serious or continuing noncompliance with this Policy
- b) any serious deviation from the provisions of the Guide [for the Care and Use of Laboratory Animals] ; or
- c) any suspension of an activity by the IACUC

IACUC suspensions of activities are cited at IV.C.6 and 7 of the Policy, and require a convened meeting of a quorum of the IACUC and the vote of a majority of the quorum present. The Institutional Official must review the reasons for suspension in consultation with the IACUC, take appropriate corrective action and report that action with full explanation to OLAW.

Through the IO, the RUSVM IACUC also reports in writing to any U.S. federal funding agency, regulatory and accreditation agencies, as applicable.

The timeline for reporting in writing to external agencies and offices is prompt and no later than within 15 days.

The IACUC Chair prepares and signs off on a semiannual report to the IO, makes recommendations to the IO pertaining to IACUC membership, and, through the IO, submits an annual report to National Institutes of Health (NIH)/Office of Laboratory Animal Welfare (OLAW)/U.S. Department of Agriculture (USDA)/St. Kitts Ministry of Agriculture and a report to OLAW of all reportable incidents, as applicable.

6.6 Protocols

The IACUC is responsible for overseeing and evaluating all aspects of Animal Care and Use, and must review proposed animal activities to ensure that the criteria for humane care and use of animals established in applicable laws, regulations, policies and guidelines stated in Section 1 of this Policy as well as RUSVM IACUC policies and SOPs are implemented and followed. In the IACUC review of these proposals, the primary goal is to facilitate compliance with University policies, and applicable laws and

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regulations consistent with the pursuit of appropriate and productive scientific, testing and teaching

endeavors. The method of protocol and protocol amendment review, decision for disapproval or approval of a protocol and maintenance of protocols are described in detail in the RUSVM IACUC Standard Operating Procedure “IACUC Protocol and Amendment Review Process”.

The IACUC conducts a thorough and comprehensive review of all new proposals and amendments to existing protocols. All existing protocols are reviewed annually to ensure that no significant deviations from established and approved procedures have occurred. When reviewing protocols, the IACUC ensures that:

- all procedures involving animals will avoid or minimize pain and distress to the animal (s);
- the principal investigator has considered alternatives to procedures that cause more than momentary pain or distress to the animals;
- the principal investigator has provided written assurance that the protocol proposed does not unnecessarily duplicate previous experiments;
- appropriate anesthetics and analgesics are used when necessary;
- personnel are properly trained to perform the proposed procedures;
- activities that involve surgery provide for appropriate pre-operative and post-operative care and that aseptic practices are followed; and
- methods of euthanasia are consistent with methods set forth by the American Veterinary Medical Association's Panel on Euthanasia.

Protocols will be approved for a period of 36 months subject to annual reviews, after which time IACUC approval for the protocol ceases. A new and complete protocol for the use of live vertebrate animals must be submitted.

In addition to annual protocol reviews, the IACUC conducts post approval monitoring (PAM) to ensure protocol compliance. The IACUC has the right to suspend an activity involving animals if it does not comply with applicable laws, regulations, policies and guidelines as well as RUSVM IACUC policies, Guidelines and SOPs.

The protocol for the use of live vertebrate animals is considered the intellectual property of the PI, available only for confidential use by IACUC members and reviewers. Accordingly, no individual may be given access to the protocol without the explicit permission of the PI.

Obligations of the Principal Investigator (PI)

No changes to any part of an IACUC-approved protocol can be implemented, until:

- 1) A Protocol Amendment has been submitted to the IACUC by the PI; and
- 2) The amendment has been approved by any of the IACUC protocol review methods; and
- 3) The PI has received the IACUC approval of the Protocol Amendment in writing

The type of review required for a Protocol Amendment may vary depending on the nature of the amendment as described in the IACUC document “IACUC Protocol and Amendment Review Process”

The PI is required to report annually on the status of the protocol, the number of animals used and that ongoing activities are conducted in accordance with the approved protocol.

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No deviations to the protocol are permitted. In the event that a protocol deviation occurs, the deviation must be documented thoroughly including the impact on animal welfare, procedures specified in the protocol and potential impact on the results of the project. Actions taken and planned corrective actions to prevent future protocol deviations must also be thoroughly described. The protocol deviation must be submitted to the IACUC promptly.

6.7 Welfare Concerns / Policy Violations

The IACUC reviews and investigates, if necessary, any concerns involving the Care and Use of Animals at RUSVM resulting from complaints or reports of noncompliance. The IACUC has the authority to suspend an activity that was previously approved, if it determines that the activity is not being conducted in accordance with the description provided by the PI in his/her protocol.

Any member of the RUSVM community who is aware of potential violations to this policy or has concerns regarding animal welfare should report this concern, anonymously if so desired, to the chair of the IACUC, the Attending Veterinarian (AV) or the IO. No member of the RUSVM community bringing forth a legitimate concern will be discriminated against or be subject to any reprisal for reporting such violations in accordance with the Whistleblower Protection Act of 1989 (5 U.S.C. 1214, 2302.) An investigation of the incident by the IACUC, the reporting of and further actions by the IACUC will be taken in accordance with IACUC policies.

6.8 Records

The IACUC also has the responsibility to maintain records in accordance with applicable laws, regulations policies and guidelines stated in section 1 of this policy.

All IACUC records that relate directly to protocols are kept for the duration of the study activity and for an additional 3 years after completion of the activity/from date of expiration of the protocol.

All RUSVM animal records will be kept on record for at least three years from the date of collection.

6.9 IACUC Policies/Guidelines/SOPs/Forms

In order to provide a framework for the Animal Care and Use Program, the IACUC has the responsibility of approving and promulgating Animal Care and Use Procedure Policies, Guidelines, SOPs and Forms. These include, but are not limited to:

- IACUC Protocol and Amendment Review Process
- Guidelines Determining IACUC oversight
- Reporting Structure of RUSVM's Animal Care and Use Program
- IACUC Training
- Concurrent or subsequent use of animals for teaching and research
 - Use of RUSVM dogs for teaching and research
 - Use of RUSVM Dogs for Research and Teaching – Preparatory Checklist
- Policy Guidelines for Categories of Animal Use and Rest Periods for RUSVM's Teaching Animals
- Requirements of Facilities that house Animals
- Reporting and Investigating Animal Welfare Concerns Policy
- Sick animal reporting flow chart
- Disaster Plan for Animals on Campus
- RUSVM Euthanasia Policy

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- Post Approval Monitoring (PAM) Policy
- SOPs for student organization activities involving animals that are not covered under a protocol.

Submission and other IACUC forms:

- Animal Protocol Review Form and IACUC Protocol forms 1-12
- Supplemental instructions for the animal protocol review form
- Protocol Review Checklist for Required Content
- Institutional Animal Care and Use Committee (IACUC) Amendment Form
- Annual renewal application for approval to use vertebrate animals - RUSVM IACUC
- RUSVM IACUC Adverse Event Form
- RUSVM IACUC Protocol Deviation Reporting Form
- IACUC Notification for collection of samples and tissues
- SOP Training Form
- Informed consent form for animal owner - use of animals in research
- Informed consent form for animal owner - use of animals in teaching

7.0 Review

This policy is subject to annual review.

Policy Approval:

Signed

Date

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Appendix I. External Documents / References

American Association of Shelter Veterinarians’ “Guidelines for Standards of Care in Animal Shelters”
<http://www.sheltervet.org/displaycommon.cfm?an=1&subarticlenbr=29>

USDA Publications, Forms and Guidance documents
https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa_publications/ct_publications_and_guidance_documents
 Animal Care Policy Manual (USDA)

Animal Welfare Act (1966) and Animal Welfare Act Regulations
<https://www.nal.usda.gov/awic/animal-welfare-act>

AVMA Guidelines on Euthanasia (2013)
<https://www.avma.org/KB/Policies/Documents/euthanasia.pdf>

Guide for the Care and Use of Agricultural Animals in Research and Teaching, 3rd Ed, 2010
https://www.aaalac.org/about/ag_guide_3rd_ed.pdf ()

Guide for the Care and Use of Laboratory Animals, 8th Ed, 2011(National Research Council))
<http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf>

Health Research Extension Act of 1985, Public Law 99-158
<http://history.nih.gov/research/downloads/PL99-158.pdf>

Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes Text with EEA relevance
<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010L0063>

Occupational Health and Safety in the Care and Use of Research Animals (NRC, 1997)
<http://www.nap.edu/openbook.php?isbn=0309052998>

Public Health Service Policy on Humane Care and Use of Laboratory Animals, 2015
<https://grants.nih.gov/grants/olaw/references/phspolicylabanimals.pdf>

ACLAM Guidelines on Adequate Veterinary Care
https://grants.nih.gov/grants/olaw/ACLAM_Adequate_Vet_Care.pdf

ACLAM Position Statement on Adequate Veterinary Care, *Journal of the American Association for Laboratory Animal Science*, November 2016
 Search article in internet search engine

AALAC position statements: <https://www.aaalac.org/accreditation/positionstatements.cfm>

St. Christopher and Nevis Chapter 11.04, Protection of Animals Act (2002)

United States Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (2002)
https://www.adsa.org/Portals/_default/SiteContent/docs/.../Appendices.pdf

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Appendix II. Definitions

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| “Ag Guide” | The Federation of Animal Science Societies’ 2010 <i>Guide for the Care and Use of Agricultural Animals in Research and Teaching</i> . |
| Animal | Any living, non-human, vertebrate animal (mammal, bird, reptile, amphibian, or fish), unless otherwise specified. |
| Animal and Plant Health Inspection Service (APHIS) | Part of the U.S. Department of Agriculture responsible for administering the Animal Welfare Act (see definition below). For more information, see www.aphis.usda.gov . |
| Animal Care (AC) | A program of APHIS. |
| Animal Facility | A University owned and operated facility where vertebrate animals are housed or held for a 12-hour period or more. |
| Animal Welfare Act and Regulations (AWAR) | Administered by APHIS, a federal law that requires that minimum standards of care and treatment be provided for certain animals bred for commercial sale, used in research, transported commercially, or exhibited to the public. |
| Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) | A private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. For more information, see www.aaalac.org . |
| Attending Veterinarian (AV) | A veterinarian with training or experience in the care and management of the species attended, and who has direct or delegated authority for activities involving animals at the University. The AV has the authority to execute the duties inherent in assuring the adequacy of veterinary care and overseeing other aspects of animal care and use. The AV clinical veterinary care responsibility can be delegated to Clinical Veterinarians. Where there are concerns about animal welfare or imminent danger to animals or human health, the AV or Clinical Veterinarian, has authority to act to protect the health and well-being of institutional animals and will make the final decision regarding the disposition of the animal. The AV is a voting member of the IACUC and reports directly to the IO. |
| Clinical Veterinarian | The Clinical Veterinarian is defined in the Reporting Structure of RUSVM’s Animal Care and Use Program SOP as either the applicable veterinarian on the on call list or the veterinarian involved in a research protocol or student club activity . The duties and responsibilities of the Clinical Veterinarian are described in the IACUC Sick Animal Reporting Flow Chart. |
| Institutional Official (IO) | The individual who is authorized to commit legally on behalf of the university that the requirements of the Animal Welfare Act and the <i>Public Health Service Policy on Humane Care and Use of Laboratory Animals</i> are met. The IACUC reports to the IO, who has the administrative and operational authority to commit institutional resources to ensure compliance with the regulations that govern the Animal Care and Use program |
| Principal | In the context of this policy, the individual with primary responsibility for a |

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| Investigator (PI) | project, including designing and implementing research or teaching involving animals. In teaching situations, this is the course coordinator. |
| Protocol | A description of the proposed procedures involving live vertebrate animals. |
| Public Health Service (PHS) Policy | The PHS Policy on Humane Care and Use of Laboratory Animals (2015) implements the Health Research Extension Act of 1985. For more information, please reference Appendix I. |
| SOP | Standard Operating Procedure |
| “The Guide” | The National Research Council’s Guide for the Care and Use of Laboratory Animals. |
| Veterinary Verification and Consultation (VVC) | Review of significant changes by AV or Clinical Veterinarians authorized by the IACUC that meet criteria as defined in the IACUC Protocol and Amendment Review Process SOP. |