

## Handbook of Operating Procedures

### USE OF ANIMALS IN RESEARCH, TRAINING, OR TESTING RELATED ACTIVITIES

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#### A. Purpose

The University of Texas Rio Grande Valley (UTRGV) recognizes the importance of animals in research and the scientific value and ethical responsibility for their humane care and use. The purpose of this policy is to outline procedures and infrastructure for the care and use of animals in research, training, or testing related activities at UTRGV consistent with requirements of the Animal Welfare Act, the Health Research Extension Act of 1985, and their respective implementing principles, policies, and regulations.

#### B. Persons Affected

This policy applies to all UTRGV faculty, staff, students, and affiliates who use live animals for research, training, including classroom and student training, or testing-related activities at a UTRGV-controlled facility or under the auspices of UTRGV. This policy also applies to UTRGV employees and affiliates responsible for the administration and oversight of the animal care program.

#### C. Policy

1. It is the policy of UTRGV to maintain an animal care program conducted in compliance with federal and state laws and regulations and UTRGV policies and procedures. Regulations governing animal care programs include, but are not limited to the requirements described in the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) based on the Health Research Extension of 1985, Public Law 99-158, Sec. 495, "Animals in Research" and the *U.S. Department of Agriculture Animal Welfare Regulations* (AWARs), 9 CFR Subchapter A, Parts 1, 2, and 3.
2. UTRGV expects all research, training and testing activities involving live vertebrate animals to be conducted following the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*, the *International Guiding Principles for Biomedical Research Involving Animals* (2012), the *Guide for the Care and Use of Laboratory Animals (the Guide)* 8<sup>th</sup> edition (or succeeding revised editions), this policy, and the UTRGV Animal Care Program and Institutional Animal Care and Use Committee (IACUC) Operations Handbook.
  - a. Research, training, and testing activities involving invertebrate animals should be performed consistent with the standards established specifically for these creatures in the UTRGV Animal Care Program and IACUC Operations Handbook.
3. Failure to comply with this policy may result in termination of research activities or disciplinary action, up to and including termination of tenure or employment.

#### **D. Procedures**

1. UTRGV will designate a Senior Official within the Division of Research as the Institutional Official (IO) responsible for the animal care and use program at UTRGV. This IO has institutional authority to ensure UTRGV is meeting the requirements of federal policies and regulations. The IO bears ultimate responsibility for the humane care and use of animals and has sufficient institutional authority to enforce related policies and commit financial resources towards the animal care program, which is supported by the Office of Laboratory Animal Resources (LAR), the Office of Research Compliance (ORC), and the IACUC. The IO is responsible for appointing members to the IACUC consistent with the requirements of the PHS Policy and the AWARs and for programmatic decisions affecting the animal care and use program. In addition, the IO is responsible for prompt reporting to the National Institute of Health, Office of Laboratory Animal Welfare (OLAW) and the U.S. Department of Agriculture (USDA), as applicable and required of reportable events.
2. The IACUC is an autonomous agent of UTRGV responsible for the general oversight, evaluation, and compliance of UTRGV's animal care and use program. The IACUC is responsible for safeguarding the welfare of animals used in research, training, and testing, regardless of the source of funding used to support animal-related activities.
  - a. The IACUC is responsible for:
    - i. Reviewing UTRGV's program for humane care and use of animals at least every six (6) months.
    - ii. Inspecting all UTRGV animal facilities at least every six (6) months (i.e., semiannually).
    - iii. Preparing reports of the IACUC evaluations conducted to the IO. The reports must meet the following criteria:
      - iii.i Be updated at least every six (6) months upon completion of required semiannual evaluations.
      - iii.ii Be maintained by the Office of Research Compliance and made available to the federal agencies upon request.
      - iii.iii Contain (1) a description of the nature and extent of UTRGV's adherence to *the Guide* and the PHS Policy, and (2) identification any departures from these provisions and a statement of the reasons for each departure.
      - iii.iv Distinguish significant deficiencies from minor deficiencies. If program or facilities deficiencies are noted, the reports must contain a reasonable and specific plan and a schedule for correcting each deficiency.
      - iii.v If any of the facilities are accredited by an accrediting body recognized by the PHS or USDA, then the report should identify those facilities as such.
    - iv. Reviewing concerns involving the care and use of animals at UTRGV to address reported issues with relevant faculty, staff, or institutional officials.

- v. Providing oversight of approved protocols, including post-approval monitoring program.
    - vi. Making recommendations to the IO regarding any aspect of the UTRGV's animal care and use program, facilities, or personnel training.
  - b. To ensure compliance with the obligations imposed by PHS Policy, AWARs, and this policy, the IACUC has the authority to:
    - i. Review and approve, require modifications in (to secure approval), or withhold approval of animal use protocols.
    - ii. Review and approve, require modifications in (to secure approval), or withhold approval of proposed modifications animal use protocols.
    - iii. Suspend or terminate an activity involving animals in accordance with the PHS Policy, AWARs, and UTRGV's policies and procedures.
    - iv. Observe or have a third party observe IACUC-approved procedures involving animals in research, training, and testing-related activities, as needed to meet its obligations of continued oversight.
- 3. UTRGV recognizes the independence of the IACUC. Animal use protocols approved by the IACUC may be subject to further review and possible disapproval by other review bodies or officials of the institution; however, no person or administrative/academic unit may override the IACUC's withholding of approval, suspension, termination, or corrective measures imposed related to an animal use protocol.
  - a. If the IACUC suspends or terminates an activity involving animals, the IO in consultation with the IACUC shall review the reasons for the suspension or termination, take appropriate corrective actions, and report that action to pertinent federal agencies and sponsors, as applicable.
- 4. The attending veterinarian (AV) is responsible for ensuring animal welfare and the provision of veterinary expertise and oversight to the animal care and use program. The AV has authority to ensure the provision of adequate veterinary care.
  - a. In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the UTRGV animal research and housing facilities.
  - b. The AV must be a voting member of the IACUC and must have a direct line of communication to the IO.
  - c. Critical aspects of the AV role, include, but are not limited to:
    - i. Providing input in all institutional plans for renovation or construction of facilities in which animals are housed or used, including the design and maintenance of animal facilities.

- ii. Providing input during protocol review to include criteria for removal of research animals from a study and responsible conduct of research activities.
  - iii. Establishing and maintaining a program of adequate veterinary care that includes the use of appropriate methods to prevent, control, diagnose, and treat animal disease and injury, and the availability of emergency, weekend, and holiday care.
  - iv. Conducting daily observations of animals to assess their health and wellbeing; provided however, that daily observation of animals may be accomplished by someone other than the AV (i.e., by LAR) when there is a mechanism of direct and frequent communication to convey timely and accurate information on problems of animal health, behavior, and well-being to the AV.
  - v. Providing guidance to principal investigators and other personnel involved in the care and use of animals with regards to handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia.
  - vi. Providing adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.
- 5. The Office of Research Compliance (ORC) is responsible for providing professional support to the IACUC operations, including without limitation:
  - a. Facilitating the onboarding and offboarding of IACUC members.
  - b. Providing training opportunities to members of the IACUC.
  - c. Coordinating all IACUC-related activities (i.e., meetings, inspections, program evaluations, etc.).
  - d. Receiving and maintaining records related to the animal care program and oversight related activities (i.e., animal use protocols, activities of the committee, minutes of meetings, records of attendance, deliberations of the committee, proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld).
  - e. Providing guidance to researchers on the protocol submission process.
  - f. Facilitating the review process of animal use protocols.
  - g. Participating in investigations of non-compliance and protocol deviation(s).
- 6. The Office of Laboratory Animal Resources (LAR) is responsible for providing laboratory animal care and husbandry in accordance with *the Guide*. Additional responsibilities of LAR include without limitation:
  - a. Conducting routine inspections of animal facilities.
  - b. Maintaining operations of and access to all UTRGV vivaria (housing and husbandry of animals, management, and enrichment programs).

- c. Reviewing and determining vivarium expenses in coordination with the IO, including the calculation and publication of animal per diems.
  - d. Conducting routine animal welfare checks and providing clinical veterinary care in coordination with the AV.
  - e. Coordinating and facilitating laboratory animal transportation.
  - f. Handling and processing lab animal orders/transfers between researchers, vendors, and other entities, to ensure regulatory compliance, including the existence of relevant contractual arrangements, and ensure animal facilities are prepared to receive or deliver such animals. No orders or transfers of laboratory animals will be made outside of LAR.
7. A significant burden of responsibility rests with investigators when engaged in animal use projects. Principal investigators (PIs) have an affirmative duty of humane care and use of animals that are supported by practical, ethical, and scientific principles. No research, training, or testing activities involving animals will be performed without the review and approval of the IACUC. PIs must submit to the IACUC a detailed written protocol that outlines all animal-related activities, and all aspects of animal care and use associated with it. Animal use protocol activities shall be consistent with those prescribed by PHS Policy, *the Guide*, the American Veterinary Medical Association (AVMA) Guidelines for Euthanasia of Animals, and AWARs. Responsibilities for PIs under this policy include, without limitation:
- a. Obtaining IACUC approval prior to the initiation of animal research, training, or testing-related activities.
  - b. Addressing IACUC requests for protocol modifications to secure project approval.
  - c. Ensuring project personnel, PI included, are trained and proficient in animal-related procedures.
  - d. Ensuring project personnel are aware of approved animal use protocol(s).
  - e. Ensuring all animal-related procedures are performed in accordance with IACUC-approved protocols and, if sponsored, congruent with procedures outlined in the sponsored project.
  - f. Providing updates to the IACUC for continuing review at least annually or more frequently, when requested.
  - g. Ensuring changes to the protocol have been approved by the IACUC prior to implementation of such changes.

- h. Ensuring that laboratory animals are identified in accordance with LAR and IACUC requirements.
  - i. Ensuring that all individuals that work with animals comply with Occupational Health Program requirements.
- 8. All known or suspected protocol deviations or instances of non-compliance with this policy are events that must be reported to the ORC and the IACUC upon discovery or notification. The ORC along with the IACUC will investigate these events and report the findings to the IO.
  - 9. Other procedures governing the IACUC actions, and the welfare of animals used in research, training, and testing are compiled in the UTRGV IACUC Handbook, which may be amended from time to time. All animal use projects must be conducted in accordance with this handbook.

#### **E. Definitions**

- 1. Animal - Any living, non-human creature used or intended for use in research, training, or testing or for related purposes.
- 2. Principal Investigator (PI) – For purpose of this policy only, the term “principal investigator” refers to the UTRGV employee with the primary responsibility for designing, managing, and overseeing research, training, or testing activities that involve animals.
- 3. Protocol - The document specifying animal care, handling, and planned experimental procedures for a proposed study, training, or testing activity that needs to be submitted and approved prior to obtaining and working with animals.
- 4. Research - A detailed study of an animal to discover information or achieve a new understanding of it. For the purposes of this policy, animals bred for use in future studies are counted as part of research.
- 5. Senior Official within the Division of Research – A senior-level university administrator, such as an assistant or associate vice president, responsible for ensuring that all research activities adhere to ethical, legal, and regulatory standards, including policies on human subjects’ protection, animal care, and research misconduct.
- 6. Testing - A procedure for critical evaluation; a means of determining the presence, quality, or accuracy of something.
- 7. Training - The action of teaching a person or group of persons about the animal’s characteristics, behaviors, care, husbandry, or response to procedures.

#### **F. Related Statutes or Regulations, Rules, Policies, or Standards**

Animal Welfare Act, 7 USC § 2131 et seq.

*Animal Welfare Act Regulations*, 9 CFR 1-3.142 administered by the U.S. Department of Agriculture: Animal and Plant Health Inspection Service (APHIS)

*Guide for the Care and Use of Laboratory Animals (the Guide)* (National Academy Press, 2011, Washington, D.C.)

*Health Research Extension Act of 1985*, Public Law 99-158, November 20, 1985, Sec. 495, "Animals in Research"

*Public Health Service Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) (based on Public Law 99-158, November 20, 1985, "Animals in Research") administered by the U.S. Department of Health and Human Services, National Institutes of Health

*The American Veterinary Medical Association Guidelines for the Euthanasia of Animals*

*U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*

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**G. Dates Reviewed or Amended**

Not applicable.