

STATEMENT OF POLICY GOVERNING THE USE OF ANIMALS IN TEACHING AND RESEARCH

The Medical Sciences Campus (MSC) of the University of Puerto Rico (UPR) acknowledges the enormous contribution that research in animals has had on the health and well-being of the human race. It also acknowledges that life of any kind should be treated with the utmost respect, dignity and compassion.

Recognizing the fact that present technology can not fully substitute for the complex interactions that exist within a living organism, and that tissue cultures, mathematical models, simulators and other current technology, while promising, can not at this time equate the benefit obtained from the use of living animals, the MSC of the UPR undertakes the responsibility of continuing to support research using animals while, at the same time, striving to increase the knowledge which will eventually make the use of animals unnecessary.

In the meantime, it will support every effort to reduce and refine the use of animals, and to replace higher species with those less complex and sophisticated that will meet the research criteria. With this in mind the Medical Sciences Campus of the University of Puerto Rico fully supports a strong Institutional Animal Care and Use Committee (IACUC), which shall oversee all animal use and ensure that appropriate laws, rules, regulations and recommendations applying to the humane care and use of animals in teaching and research be followed in the most appropriate manner.

These laws, rules, regulations and recommendations shall include, but will not be limited to those expressed in the AMA, NIH Guide, PHS policy, AVMA expert panel on euthanasia, etc., as described below.

I. INTRODUCTION

As long as animals continue to be used in research and teaching, scientist and teachers have a responsibility to adhere to the principle that these animals be treated humanely by ensuring their health and well-being, and by minimizing their pain and suffering. While there are numerous laws and regulations governing the care and use of laboratory animals, enforcement and compliance is primarily through self regulation both at the institutional and at the individual level.

The Medical Sciences Campus Policy on the Use and Care of Animals is based upon three regulatory agencies:

1. United States Department of Agriculture which uses The Animal Welfare Act (as amended) as its regulatory document.

The United States Department of Agriculture (USDA) is responsible for implementing The Animal Welfare Act (AWA). The Act only applies to dogs, cats, rabbits, hamsters, guinea pigs, non human primates and marine mammals (rats, mice and farm animals are not included). Although research facilities are required to be registered, to have their suppliers licensed, and to undergo at least semi-annual inspections by the Animal and Plant Health Inspection Service (APHIS) veterinarians, the Act does not apply

directly to the conduction of research using animals. The AWA was amended in 1970 and 1976, and underwent a major revision in December 1985. Although NIH is not responsible for enforcing the AWA, requirements for compliance with it have been incorporated into any and all research conducted or supported by any component of the Public Health Service.

2. The US Public Health Service (PHS)

In 1985, another law was passed by Congress known as the Health Research Extension Act which applied to all research funded by PHS of which NIH is part.

The PHS Policy requires compliance with the AWA and with the recommendations of the NIH "Guide for the Care and Use of Laboratory Animals". It also requires each institution to provide NIH with an assurance which gives institutions detailed policies for research, training, testing, education, experimentation or demonstration purposes. If an institution fails to comply, NIH can withdraw approval and suspend or terminate all PHS supported research. Individual investigators could also be disqualified from receiving PHS awards. Thus, this Policy requires that individual institutions assume responsibility for the quality of their animal research program and for the conduct of their investigators and animal care personnel. The new PHS policy covered all vertebrates used in research with emphasis on the responsibility of awarded institutions to train staff for the management of their animal programs. This Policy gives institutions three options for obtaining NIH approval:

- a) Accreditation by the American Association for Accreditation of Laboratory Animal Care (AAALAC).
- b) An assurance that the institution's own Institutional Animal Care and Use Committee (IACUC) had found the institution in full compliance with the "Guide".
- c) Provisional assurance of plans for correction, in the case that deficiencies found by the Committee's semi-annual inspections were reported to the Office for Protection from Research Risks (OPRR) in the institution's annual assurance update report.

The final version of the PHS policy, "The Public Health Service Policy on Humane Care and Use of Laboratory Animals" became effective on January 1, 1986. Subsequent to the revision, Congress enacted the Health Research Extension Act, which added several provisions to PHS Policy. Key elements of PHS Policy now include:

- a) Negotiation of Animal Welfare Assurance, which includes: commitments by the awardee Institution to support its animal care and use program, appropriation of staff training, and to set up an occupational health program for employees.
- b) Establishment, according to specified criteria, of an Institutional Animal Care and Use Committee having defined responsibilities.
- c) Detailed requirements for the submission of applications for awards.

d) Record keeping requirements to ensure clear accountability for the quality of the program.

e) Reporting requirements to enable funding agencies and OPRR to exercise oversight of the entire system.

3. The American Association for the Accreditation of Laboratory Animal Care (AAALAC).

AAALAC was established in 1965 as a voluntary program for the accreditation of laboratory animal care facilities and programs.

Under PHS Policy and USDA Regulations, the IACUC must inspect all institutional animal facilities every six months. These inspections provide an ongoing mechanism for ensuring that the institution maintains compliance with the applicable animal care and use policies, guidelines and laws. Inspections can also benefit programs for animal care by serving in an educational function for the animal care personnel, research staff and IACUC members. Also, by giving the facility personnel a prior warning, the IACUC can assist an institution in preparing for subsequent visits by outside inspectors. The interaction of an IACUC and the animal care personnel at their institution should be constructive, and not adversarial, as both ultimately share the same goals of providing good animal care.

II. IACUC

The role of the Institutional Animal Care and Use Committee (IACUC) is to ensure that all research, training/educational programs utilizing live animals are conducted by qualified personnel with the health, well-being and relief of pain and suffering of the animals of primary importance. Each institution which falls under the authority of the Animal Welfare Act and/or receives PHS support for research and teaching involving laboratory animals must operate a program with clear lines of authority and responsibility, a properly functioning IACUC, implement procedures for self monitoring, for adequate veterinary care, for an adequate program of occupational health, sound animal husbandry practices, and appropriate maintenance of facilities for housing animals. The IACUC must have at least five members, including a veterinarian with program responsibilities, a scientist experienced in laboratory animal research, a non-scientist and an individual who has no other affiliation with the institution besides membership in the IACUC.

The IACUC for the Medical Sciences Campus institution must have the full support of the Institutional Official (Chancellor) responsible for the Program. The IACUC has the authority to suspend research activities on the campus.

A. IACUC FUNCTIONS

1. Review, at least once every 6 months, the research facility's program, using USDA Regulations/"Guide" as basis.

2. Inspect, at least once every 6 months, all of the animal facilities, including animal study areas/satellite facilities, using USDA Regulations and the "Guide" as a basis.
3. Prepare reports of IACUC evaluations and submit the reports to the Institutional Official (Chancellor).
4. Review and investigate legitimate concerns or compliance involving the care and use of animals at campus research facilities including those from the general public, facility personnel or other employees.
5. Make recommendations to the Institutional Official regarding any aspect of the research facility's animal program, facilities or personnel training.
6. Review and approve, require modifications in, or withhold approval of those components of proposed activities (research, training, teaching, demonstrations, etc.) related to the care and use of animals.
7. Review and approve, require modifications in, or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.
8. suspend an activity involving animals when necessary; take corrective action and report its actions to the funding agency and USDA.

A. PROTOCOL SUBMISSION

1. The Principal Investigator should submit the entire proposal and a complete Animal Study Proposal Form (enclosed) for consideration by the IACUC at least two weeks before the monthly IACUC meeting. **Should submit at least two copies of the Animal Study Proposal Form.**
2. Principal Investigator must submit an Annual Continuation Review Form on the anniversary of their approval. the IACUC approves protocols on an annual basis. the IACUC will supply the appropriate forms to the investigator at least 30 days prior to the anniversary date.
3. Principal Investigator must submit an Animal Use Protocol Minor Amendments Form for consideration by the IACUC if their proposal require modifications related to: 1) change in animal specie (justify the number of animals requested), 2) change in animal housing, 3) change in animal number (justify the number of animals requested), 4) addition/deletion/change in protocol, and 5) addition/change in personnel (must be accompanied by a qualification form).

B. PROTOCOL APPROVAL (IACUC CRITERIA)

1. Activities must be in accordance with USDA Regulations/PHS Policy.
2. Activities must avoid/minimize discomfort/distress/pain. If pain/distress is caused, appropriate sedation, analgesia or anesthesia must be used. The attending veterinarians must be involved in the planning. Use of paralytics without anesthesia is prohibited. Animals with chronic/severe or unrelievable pain will be humanely killed.

3. Survival surgery must meet requirements for sterile surgery and pre/post operative care. Investigators can not repeatedly use one animal for several major operative procedures from which it will recover, unless specified conditions are met.
4. Euthanasia methods must be consistent with USDA Regulations/AVMA Panel on Euthanasia recommendations.
5. Animal living conditions must be consistent with regulatory standards of housing, feeding and care. Conditions must be enforced by the veterinarian, or scientist with appropriate expertise.
6. Alternatives to painful procedures must be considered and this also must be documented if animals will experience any pain or suffering.
7. Investigators must provide a written narrative of their methods/sources.
8. Investigators must provide assurance that activities do not unnecessarily duplicate previous efforts.
9. All personnel working with the animals must be appropriately qualified and most take periodic training on the species with which they are working.
10. All deviations from requirements must be justified in writing, based on scientific reasons and approved by the IACUC.

C. INSTITUTIONAL TRAINING PROGRAM

Training and instruction of personnel must include guidance in several areas:

1. Humane methods of animal maintenance and experimentation, including:
 - The basic needs of each species of animal.
 - Proper handling and care for the various species of animals used by the facility.
 - Proper pre and post procedural care of animals.
 - Aseptic surgical methods and procedures.
2. Stress concepts of research and testing methods which limit the use of animals or minimize animal distress.
3. Proper use of anesthetics, analgesics and tranquilizers for any species of animal used by the facility.
4. Description of procedures whereby deficiencies in animal care and treatment can be reported. This includes deficiencies reported by any employee of the facility. No facility employee, IACUC member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of regulations or standards under the AWA.
5. Utilization of services available to provide information:

- On appropriate methods of animal care and use.
- On alternatives to the use of live animals in research.
- Unintended and unnecessary duplication of research involving animals.