CHAPTER VII:

POLICY ON HUMANE

CARE AND USE OF

POLICY ON THE HUMANE CARE AND USE OF ANIMALS

I. Policy:
It is the Policy of the Public Health Service (PHS) to require institutions to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training, and biological testing activities (hereinafter referred to as activities) conducted or supported by the PHS. The PHS endorses the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training" developed by the Interagency Research Animal Committee. This Policy is intended to implement and supplement those Principles.

II. Applicability
This Policy is applicable to all PHS-conducted or supported activities involving animals, whether the activities are performed at a PHS agency, an awardee institution, or any other institution and conducted in the United States, the Commonwealth of Puerto Rico, or any territory or possession of the United States. Institutions in foreign countries receiving PHS support for activities involving animals shall comply with this Policy, or provide evidence to the PHS that acceptable standards for the humane care and use of the animals in PHS-conducted or supported activities will be met. No PHS support for an activity involving animals will be provided to an individual unless that individual is affiliated with or sponsored by an institution which can and does assume responsibility for compliance with this Policy, unless the individual makes other arrangements with the PHS. This Policy does not affect applicable state or local laws or regulations which impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act, and other Federal statutes and regulations relating to animals.

III. Definitions

- *Animal* - Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.
  Animal Facility - Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. A satellite facility is any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 24 hours.
- *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 Code of Federal Regulations (CFR), Title 9, Chapter 1, Subchapter A, Parts 1, 2, and 3, and are administered by the U.S. Department of Agriculture.
- *Animal Welfare Assurance* - The documentation from an institution assuring institutional compliance with this Policy.
- *Guide - Guide for the Care and Use of Laboratory Animals*, National Academy Press, 1996, Washington, D.C., or succeeding revised editions.
- *Institution* - Any public or private organization, business, or agency (including components of Federal, state, and local governments).
- *Institutional Official* - An individual who signs, and has the authority to sign the institution's Assurance, making a commitment on behalf of the institution that the requirements of this Policy will be met.
- *Public Health Service* - The Public

the IACUC evaluation shall be submitted to OLAW with the Assurance.

C. Institutional Animal Care and Use Committee (IACUC)

1. The Chancellor through the Vice Provost

those components of PHS-conducted or supported activities related to the care and use of animals as specified in IV.C. of this Policy;

7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities; and
8. Be authorized to suspend an activity involving animals in accordance with the specifications set forth in IV.C.6 of this Policy.

E. Review of PHS-Conducted or Supported Research Projects or any other use of vertebrate animals

1. In order to approve proposed research projects or proposed significant changes in ongoing research projects, the IACUC shall conduct a review of those components related to the care and use of animals and determine that the proposed research projects are in accordance with this Policy. In making this determination, the IACUC shall confirm that the research project will be conducted in accordance with the Animal Welfare Act insofar as it applies to the research project, and that the research project is consistent with the *Guide* unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the research project conforms with the institution's Assurance and meets the following requirements:
    a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
    b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
    c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
    d. 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 the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
    e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
    f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
    g. Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Pan7d.imals will

information. However, the application or proposal must contain a statement to that effect. If there are significant changes in the information, then the application or proposal must specifically identify them and state the reasons for the changes.

2. Institutions That Have an Approved Assurance

   Applications or proposals (competing and non-competing) covered by this Policy from institutions which have an approved Assurance on file with OLAW shall include verification of approval (including the date of the most recent approval) by the IACUC of those components related to the care and use of animals. For competing applications or proposals only, such verification may be filed at any time prior to award unless specifically required earlier by the funding component. If verification of

V. Implementation by PHS

A. The Office of Laboratory Animal Welfare (OLAW) is responsible for the general administration and coordination of this Policy and will:

1. Request and negotiate, approve or disapprove, and, as necessary, restrict or withdraw approval of Assurances;
2. Distribute to Scientific Review Administrators of initial review and technical evaluation groups, and to PHS awarding units, lists of institutions [domestic and foreign] that have an approved Assurance;
3. Advise awarding units and awardee institutions concerning the implementation of this Policy;
4. Evaluate allegations of noncompliance with this Policy;
5. Have the authority to review and approve or disapprove waivers to this Policy (see V.D. of this Policy); and
6. Conduct site visits to selected institutions.

B. Responsibilities of PHS Awarding Units

PHS awarding units may not make an award for an activity involving animals unless the prospective awardee institution and all other participating institutions have approved Assurances on file with OLAW, and the awardee institution has provided verification of approval by the IACUC of those components of the application or proposal related to the care and use of animals. If any one of these institutions does not have an approved Assurance on file with OLAW, the awarding unit will ask OLAW to negotiate an Assurance with the institution(s)

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and service while ensuring that all use of live vertebrates is adequately justified and conducted by knowledgeable people using the most appropriate methodology. In acknowledgement of the scientific and ethical responsibility of the University for the humane care of animals, and in the interest of ensuring the high quality of university research and educational pursuits, the

the proposal. If any committee member requests a full review, then the designated review is cancelled, and the proposal must undergo full review. If no one on the committee objects, then the chair will designate a single reviewer for the proposal. This reviewer will make recommendations to the chair for approval or refer the proposal back to the full committee for a full review. Use of designated review is at the discretion of the IACUC. No activities involving the use of vertebrate animals shall be initiated nor shall such animals be obtained until the proposal has received committee approval.
The formal actions of the IACUC upon reviewing a proposals shall be as follows:
Approval – indicates that the applicant may obtain animals and begin research, and that the project meets IACUC standards for the care and use of vertebrate animals

Approval withheld pending – Indicates that the approval of the committee has been withheld, pending revisions of specific points. Animals may not be obtained or used until all the outlined provisions have been submitted to and approved by the committee

Disapproval – Indicates that the proposed activity does not meet university or federal guidelines for the care and use of vertebrate animals. Animals may not be obtained, nor can any activity proceed. The investigator shall have the opportunity to respond in person or in writing to the committee. If the IACUC gives a proposed project an *Approval Withheld Pending* status, the investigator must contact the IACUC Chair regarding the required action within sixty (60) days, or the proposal will be withdrawn from further committee action and considered to be Disapproved.

The IACUC approves the protocols for a period of three years, pending successful annual review. In the reviews at the end of each year, the principal investigator must provide the committee with a brief summary of the research conducted in the past year, a table detailing the numbers and species used, and a statement assuring the committee that the investigator is familiar with the definition of significant changes, and that no such changes have occurred.
After the third report is submitted (end of year three), the principal investigator must submit a new protocol form and have the procedures reviewed again, as if it were a new protocol.
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