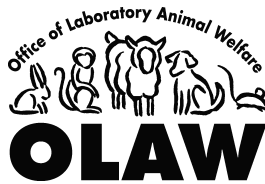




Public Health Service Policy on Humane Care and Use of Laboratory Animals



Revised August, 2002

Preface

This 2002 reprint of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals reflects the August 7, 2002 PHS Policy amendment permitting institutions with PHS Animal Welfare Assurances to submit verification of Institutional Animal Care and Use Committee (IACUC) approval for competing applications or proposals subsequent to peer review but prior to award (67 FR 51289). New footnotes (6 and 12) are incorporated to provide institutions with the option of coding the names of IACUC members in materials routinely submitted to the Office of Laboratory Animal Welfare (OLAW). Citations and addresses are also updated in this reprint, and language specifying that information be submitted on institutional letterhead or in letter form is eliminated to allow for electronic submission of information to OLAW in the future.

OLAW, which has responsibility for the general administration and coordination of the Policy, provides specific guidance, instruction, and materials to institutions that must comply with the Policy. For supplemental materials please contact OLAW at the National Institutes of Health, RKL1, Suite 360, MSC 7982, 6705 Rockledge Drive, Bethesda, Maryland 20892-7982 (for express or hand delivered mail, use zip code 20817) or visit the OLAW website at <http://grants.nih.gov/grants/olaw/olaw.htm>.

This reprint includes the Health Research Extension Act of 1985, Public Law 99-158, "Animals In Research" (November 20, 1985), which provides the statutory mandate for the PHS Policy. Also included in this reprint are the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training. The U.S. Principles were promulgated in 1985 by the Interagency Research Animal Committee and adopted by U.S. Government agencies that either develop requirements for or sponsor procedures involving the use of vertebrate animals. The Principles were incorporated into the PHS Policy in 1986 and continue to provide a framework for conducting research in accordance with the Policy.

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

Sec. 495.

(a) The Secretary, acting through the Director of NIH,

“(B) keep appropriate records of reviews conducted under subparagraph (A); and

“(C) for each review conducted under subparagraph (A), file with the Director of NIH at least annually (i) a certification that the review has been conducted, and (ii) reports of any violations of guidelines established under subsection (a) or assurances required under paragraph (1) which were observed in such review and which have continued after notice by the committee to the research entity involved of the violations.

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

The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires *in vivo* experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training proc

- VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must 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. In any case, veterinary care shall be provided as indicated.
- VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.
- IX. Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

Public Health Service Policy on Humane Care and Use of Laboratory Animals

I. Introduction

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

A. **Animal** – Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.

B. **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.

C. **Animal Welfare** [Public Law 102-455, 33916.5 3.342w 1.242](#)

- c. the qualifications, authority, and responsibility of the veterinarian(s) who will participate in the program and the percent of time each will contribute to the program;
- d. the membership list of the Institutional Animal Care and Use Committee(s) (IACUC) established in accordance with the requirements set forth in IV.A.3. of this Policy;³
- e. the procedures which the IACUC will follow to fulfill the requirements set forth in this Policy;
- f. the health program for personnel who work in laboratory animal facilities or have frequent contact with animals;
- g. a synopsis of training or instruction in the humane practice of animal care and use, as well as training or instruction in research or testing methods that minimize the number of animals required to obtain valid results and minimize animal distress, offered to scientists, animal technicians, and other personnel involved in animal care, treatment, or use;
- h. the gross square footage of each animal facility (including satellite facilities), the species housed therein and the average daily inventory, by species, of animals in each facility; and
- i. any other pertinent information requested by OLAW.

2. Institutional Status

Each institution must assure that its program and facilities are in one of the following categories:

Category 1 – Accredited by the [Association for Assessment and Accreditation of Laboratory Animal Care International \(AAALAC\)](#). All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by AAALAC, or another accrediting body recognized by PHS.⁴ All of the institution's programs and facilities (including satellite facilities) for activities involving animals have also been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months, in accordance with IV.B.1. and 2. of this Policy, and reports prepared in accordance with IV.B.3. of this Policy.

³ The name Institutional Animal Care and Use Committee (IACUC) as used in this Policy is intended as a generic term for a committee whose function is to ensure that the care and use of animals in PHS-conducted or supported activities is appropriate and humane in accordance with this Policy. However, each institution may identify the committee by whatever name it chooses.

⁴ As of the 2002 revision of this Policy, the only accrediting body recognized by PHS is the [Association for Assessment and Accreditation of Laboratory Animal Care International \(AAALAC\)](#).

Category 2 – Evaluated by the Institution. All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months, in accordance with IV.B.1. and 2. of this Policy, and reports prepared in accordance with IV.B.3. of this Policy. The most recent semiannual report of the IACUC evaluation shall be submitted to OLAW with the Assurance.

3. Institutional Animal Care and Use Committee (IACUC)

- a. The Chief Executive Officer shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures.⁵
- b. The Assurance must include the names,⁶ position titles, and credentials of the IACUC chairperson and the members. The committee shall consist of not less than five members, and shall include at least:
 - (1) one Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program authority and responsibility for activities involving animals at the institution (see IV.A.1.c.);
 - (2) one practicing scientist experienced in research involving animals;
 - (3) one member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy); and
 - (4) one individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution.
- c. An individual who meets the requirements of more than one of the categories detailed in IV.A.3.b.(1)-(4) of this Policy may fulfill more than one requirement. However, no committee may consist of less than five members.

⁵ The [Health Research Extension Act of 1985](#) requires the IACUC to be appointed by the chief executive officer (CEO) of the entity for which the committee is established. OLAW considers the CEO to be the highest operating official of the organization (such as the President of a University). If the CEO delegates authority to appoint the IACUC then the delegation must be specific and in writing. The CEO may or may not be the Institutional Official as defined by this Policy (see definition at III.G.).

⁶ Institutions may, at their discretion, represent the names of members other than the chairperson and veterinarian with program authority (see IV.A.3.), by using numbers or other symbols in submissions to OLAW. Sufficient information for OLAW to determine that all appointees are appropriately qualified must be provided. The identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

B. Functions of the Institutional Animal Care and Use Committee

As an agent of the institution, the IACUC shall with respect to PHS,6a1 0 Td(e C)T.5344 01c

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housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use o

4. The IACUC shall notify investigators and the institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
5. The IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with IV.C.1.-4. at least once every three years.
6. The IACUC may 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 IV.C.1.a.-g. of this Policy.¹¹ The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present.
7. If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW.
8. Applications and proposals that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the institution. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

D. Information Required in Applications and Proposals for Awards Submitted to PHS

1. All Institutions

Applications and proposals (competing and non-competing) for awards submitted to PHS that involve the care and use of animals shall contain the following information:

- a. identification of the species and approximate number of animals to be used;

¹¹ This Policy requires that Assured institutions base their programs of animal care and use on the [Guide for the Care and Use of Laboratory Animals](#) and that they comply with the applicable regulations (9 CFR, Subchapter A) issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The [Guide](#) may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

- b. rationale for involving animals, and for the appropriateness of the species and numbers used;
- c. a complete description of the proposed use of the animals;
- d. a description of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and
- e. a description of any euthanasia method to be used.

Non-competing applications and contract proposals for other than full and open competitions need not repeat the information required by IV.D.1.a.-e. if the information was complete in the last competing application or proposal and there are no significant changes to that 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) must include the following information:

by OLAW. Upon such request, the institution shall prepare the Assurance as instructed by OLAW and in accordance with IV.A. of this Policy. The authorized IACUC shall review those components of the application or proposal as required by IV.C. of this Policy. Upon IACUC approval of those components of the application or proposal the institution shall submit the Assurance to OLAW.

E. Recordkeeping Requirements

1. The awardee institution shall maintain:
 - a. a copy of the Assurance which has been approved by the PHS;
 - b. minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations;
 - c. records of applications, pr

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) before an award is made. No award shall be made until all required Assurances have been submitted by the institution(s), been approved by OLAW, and the institution(s) have provided verification of approval by the IACUC of those components of the application or proposal related to the care and use of animals.

C. Conduct of Special Reviews/ Site Visits

Each awardee institution is subject to review at any time by PHS staff and

Office of Laboratory Animal Welfare
National Institutes of Health
Department of Health and Human Services
RKL I, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982