

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

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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) 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 (IRAC). This policy is intended to implement and supplement those Principles.

Applicability

This policy is applicable to all PHS-approved activities involving animals, whether the activities are performed at 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 humane care and use of the animals in PHS-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 for PHS-supported activities, or 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.

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 Act
Public Law 89-544, 1966, as amended, (P.L. 91-579 and P.L. 94-279) 7 U.S.C. 2131 et seq. Implementing regulations are published in the Code of Federal Regulations (CFR), Title 9, Subchapter A, Parts 1, 2, 3 and 4, and are administered by the U.S. Department of Agriculture.
- D. Animal Welfare Assurance or Assurance
The documentation from an awardee or a prospective awardee institution assuring institutional compliance with this policy.
- E. Guide
Guide for the Care and Use of Laboratory Animals, DHEW, NIH Pub. No. 78-23, 1978 edition or succeeding revised editions.
- F. Institution
Any public or private organization, business, or agency (including components of Federal, state and local governments).
- G. Institutional Official
An individual who 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.
- H. Public Health Service
The Public Health Service includes the Alcohol, Drug Abuse, and Mental Health Administration, the Centers for Disease Control, the Food and Drug Administration, the Health Resources and Services Administration, and the National Institutes of Health.

I. Quorum

A majority of the members of the Institutional Animal Care and Use Committee.

Implementation by Awardee Institutions

A. Animal Welfare Assurance

No activity involving animals will be supported by the PHS until the institution conducting the activity has provided a written Assurance acceptable to the PHS, setting forth compliance with this policy for PHS-supported activities. Assurances shall be submitted to the Office for Protection from Research Risks (OPRR), Office of the Director, National Institutes of Health, 9000 Rockville Pike, Building 31, Room 4B09, Bethesda, Maryland 20205. The Assurance shall be typed on the institution's letterhead and signed by an institutional official. OPRR will provide the applicant institution with necessary instructions and an example of an acceptable Assurance. All Assurances submitted to the PHS in accordance with this policy will be evaluated by OPRR to determine the adequacy of the institution's proposed program for the care and use of animals in PHS-supported activities. On the basis of this evaluation OPRR may approve or disapprove the Assurance, or negotiate an approvable Assurance with the institution. Approval of an Assurance will be for a specified period of time (no longer than five years) after which **time the institution must submit a new Assurance to OPRR.** OPRR may limit the period during which any particular approved Assurance shall **remain effective or otherwise condition**, restrict, or withdraw approval. Without an applicable PHS approved Assurance no PHS-supported activity involving animals at the institution will be permitted to continue.

1. Institutional Program for Animal Care and Use

The Assurance shall fully describe the institution's program for the care and use of animals in PHS-supported activities. The PHS requires institutions to use the *Guide for the Care and Use of Laboratory Animals (Guide)* as a basis for developing and implementing an institutional program for activities involving animals. The program description must include the following:

- a, a list of every branch and major component of the institution, as well as a list of every branch and major component of any other institution which is to be included under the Assurance;

- b. the lines of authority and responsibility for administering the program and ensuring compliance with this policy;
- c. the qualifications, authority and responsibility of the veterinarian(s) who will participate in the program;
- d. the membership list of the Institutional Animal Care and Use Committee (IACUC) established in accordance with the requirements set forth in IV.A.3.;
- e. the procedures which the IACUC will follow to fulfill the requirements set forth in IV. B.;
- f. the health program for personnel who work in laboratory animal facilities or have frequent contact with animals;
- g. 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
- h. any other pertinent information requested by OPRR.

2. Institutional Status

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

- **Category 1**—Accredited by the American Association for the Accreditation of Laboratory Animal Care (AAALAC). All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by AAALAC, or other accrediting body recognized by PHS.²
- **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 each year. The IACUC shall use the *Guide for the Care and Use of Laboratory Animals* as a basis for evaluating the institution's program and facilities. A report of the IACUC evaluation shall be submitted to the institutional official and updated on an annual basis.³The initial report shall be submitted to

²The 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-supported activities is appropriate and humane in accordance with this policy. However, each institution may identify the committee by whatever name it chooses. Membership and responsibilities of the IACUC are set forth in IV.A.3 and IV.B.

³As of the issuance date of this policy the only accrediting body recognized by PHS is the American Association for Accreditation of Laboratory Animal Care (AAALAC).

⁴The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities. The IACUC may invite ad hoc consultants to conduct or assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report.

OPRR with the Assurance. Annual reports of the IACUC evaluation shall be maintained by the institution and made available to OPRR upon request. The report must contain a description of the nature and extent of the institution's adherence to the *Guide* and this policy.⁴ **The report must identify specifically any departures from provisions of the Guide and this policy, and state the reasons for each departure. If program or facility deficiencies are noted, the report must contain a reasonable and specific plan and schedule for correcting each deficiency. The report must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, in the judgment of the IACUC and the institutional official, is or may be a threat to the health or safety of the animals. Failure of the IACUC to conduct an annual evaluation and submit the required report to the institutional official may result in PHS withdrawal of its approval of the Assurance.**

3. Institutional Animal Care and Use Committee (IACUC)

- a. Each institution 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.
- b. The Assurance must include the names, 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 responsibility for activities involving animals at the institution;
 - (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) may fulfill more than one requirement, However, no committee may consist of less than five members,

B. Functions of the Institutional Animal Care and Use Committee

As an agent of the institution the IACUC shall, with respect to PHS-supported activities:

1. review at least annually the institution's program for humane care and use of animals;
2. inspect at least annually all of the institution's animal facilities, including satellite facilities;
3. review concerns involving the care and use of animals at the institution;
4. make recommendations to the institutional official regarding any aspect of the institution's animal program, facilities or personnel training;
5. review and approve, require modifications in (to secure approval) or withhold approval of those sections of PHS applications or proposals related to the care and use of animals as specified in IV.C.;
6. 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
7. be authorized to suspend an activity involving animals in accord with specifications set forth in IV.C.5.

C. Review of PHS Applications and Proposals

1. In order to approve applications and proposals or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those sections related to the care and use of animals and determine that the proposed activities are in accord with this policy. In making this determination, the IACUC shall confirm that the activity will be conducted in accord with the Animal Welfare Act insofar as it applies to the activity, and that the activity is consistent with the *Guide* unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the activity 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 sacrificed at the

⁴If some of the institution's facilities are accredited by AAALAC or other accrediting body recognized by PHS, the report should "identify those facilities and need not contain any further information about evaluation of those facilities"

- 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 nonmedical 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) Panel on Euthanasia,⁵ unless a deviation is justified for scientific reasons in writing by the investigator.
2. Prior to the review, each IACUC member shall be provided with a list of applications and proposals to be reviewed. Those sections of applications and proposals that relate to the care and use of animals shall be available to all IACUC members, and any member of the IACUC may upon request obtain full committee review of those sections. If full committee review is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, shall review those sections and have the authority to approve, require modifications in (to secure approval) or request full committee review of those sections. If full committee review is requested, approval of those sections may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of an application or proposal in which the member has a conflicting interest (e.g., is personally involved in the project), except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.
 3. The IACUC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of an application or proposal or vote with the IACUC.
4. The IACUC shall notify investigators and the institution in writing of its decision to approve or withhold approval of those sections of applications or proposals 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 application or proposal, 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 applications and proposals covered by this policy at appropriate intervals as determined by the IACUC, but not less than 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.** 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 OPRR.
 8. Applications and proposals that have been approved by the IACUC maybe subject to further appropriate review and approval by officials of the institution. However, those officials may not approve those sections of an application or proposal related to the care and use of animals if they have not been approved by the IACUC.
- D. Information Required in Applications and Proposals Submitted to PHS
1. All Institutions

Applications and proposals 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;
 - b. rationale for involving animals, and for the appropriateness of the species and numbers to be used;
 - c. a complete description of the proposed use of the animals;
 - d. assurance that discomfort and injury to animals will be limited to that which is unavoidable.

⁵Journal of the American Veterinary Medical Association (JAVMA), 1978, Vol. 173, No. 1, pp. 59-72, or succeeding revised editions.

able 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.

2. Institutions That Have an Approved Assurance

Applications or proposals covered by this policy from institutions which have an approved Assurance on file with OPRR shall include verification of approval by the IACUC of those sections related to the care and use of animals. With the authorization of PHS, such verification may be filed at a time not to exceed 60 days after submission of applications or proposals.⁶

If verification of IACUC approval is submitted subsequent to the submission of the application or proposal, the verification shall state the modifications, if any, required by the IACUC. The verification shall be signed by an individual authorized by the institution, but need not be signed by the institutional official who signed the Assurance.

3. Institutions That Do Not Have an Approved Assurance

Applications and proposals involving animals from institutions that do not have an approved Assurance on file with OPRR shall contain a declaration that the institution will establish an IACUC and submit an Assurance upon request by OPRR. After OPRR has requested the Assurance, the institution shall establish an IACUC as required by IV.A.3. and the IACUC shall review those sections of the application or proposal as required by IV.c. The institution shall then submit to OPRR the Assurance and verification of IACUC approval. The verification shall state the modifications, if any, required by the IACUC. The verification shall be signed by an individual authorized by the institution, but need not be signed by the institutional official who signed the Assurance.

E. Recordkeeping

1. The awardee institution shall maintain:
 - a. an Assurance approved by the PHS;
 - b. minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations;

- c. records of applications, proposals and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld;

- d. records of any IACUC reports and recommendations as forwarded to the institutional official; and

- e. records of accrediting body determinations.

2. All records shall be maintained for at least three years; records that relate directly to applications, proposals, and proposed significant changes in ongoing activities reviewed and approved by the IACUC shall be maintained for the duration of the activity and for an additional three years after the completion of the activity. All records shall be accessible for inspection and copying by authorized OPRR or other PHS representatives at reasonable times and in a reasonable manner.

F. Reporting Requirements

1. On or before each anniversary of approval of its Assurance, the institution shall report in writing to OPRR:

- a. any change in the institution's program or facilities which would place the institution in a different category than specified in its Assurance (see IV.A.2.);

- b. any change in the description of the institution's program for animal care and use as required by IV. A.1.a.-h.;

- c. any changes in IACUC membership; and

- d. if the institution's program and facilities are in Category 2 (see IV.A.2.), verification that the IACUC has conducted an annual evaluation of the institution's program and facilities and submitted the evaluation to the institutional official.

2. Institutions that have no changes to report as specified in IV.F. 1.a.-c. shall submit a letter to OPRR stating that there are no changes.

3. Institutions shall provide OPRR promptly 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*; or

- c. any suspension of an activity by the IACUC.

Implementation by PHS

A. Responsibilities of OPRR

OPRR is responsible for the general administration and coordination of this policy and will:

1. request and negotiate, approve or disapprove,

⁶Until further notice PHS hereby authorizes all institutions with approved Assurances to file verification of IACUC approval either along with the application or proposal or within 60 days of submission of the application or proposal. From time to time PHS will reevaluate this blanket authorization. Any decision to withdraw this authorization will take place only after ample opportunity is provided for comment by the public.

- and, as necessary, withdraw approval of Assurances;
2. distribute to executive secretaries of initial review and technical evaluation groups, and to PHS awarding units, lists of institutions 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.); 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 institution submitting the application or proposal is on the list of institutions that have an approved Assurance on file with OPRR, and the institution has provided verification of approval by the IACUC of those sections of the application or proposal related to the

care and use of animals in PHS-supported activities. If an institution is not listed, the awarding unit will ask OPRR to negotiate an Assurance with the institution before an award is made. No award shall be made until the Assurance has been submitted by the institution, approved by OPRR, and the institution has provided verification of approval by the IACUC of those sections of the application or proposal related to the care and use of animals in PHS-supported activities.

C. Conduct of Special Reviews/Site Visits

Each awardee institution is subject to review at anytime by PHS staff and advisors, which may include a site visit, in order to assess the adequacy of the institution's compliance with this policy.

D. Waiver

Institutions may request a waiver of a provision or provisions of this policy by submitting a request to OPRR. No waiver will be granted unless sufficient justification is provided and the waiver is approved in writing by OPRR.