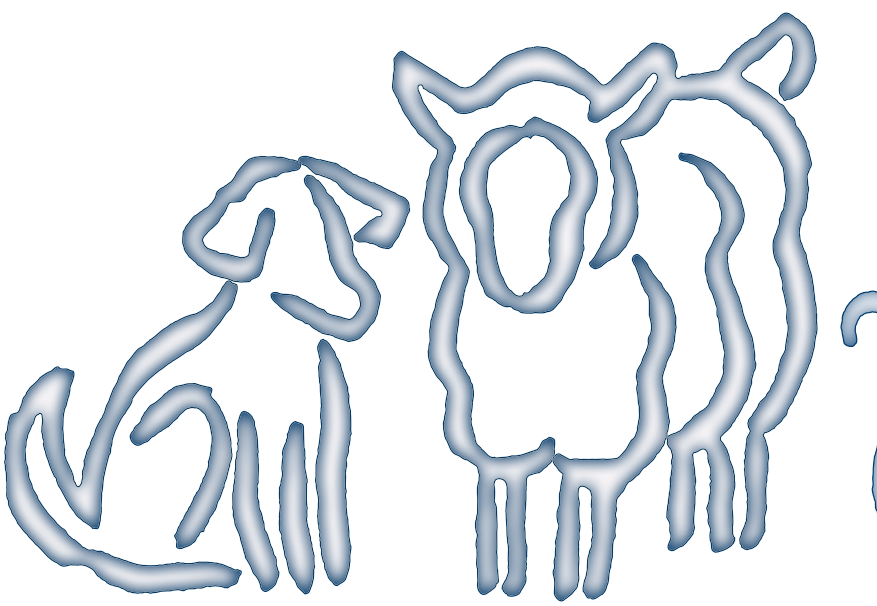
U.S. Department of Health
and Human Services

National Institutes of Health
Office of Laboratory Animal Welfare

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



Revised 2015

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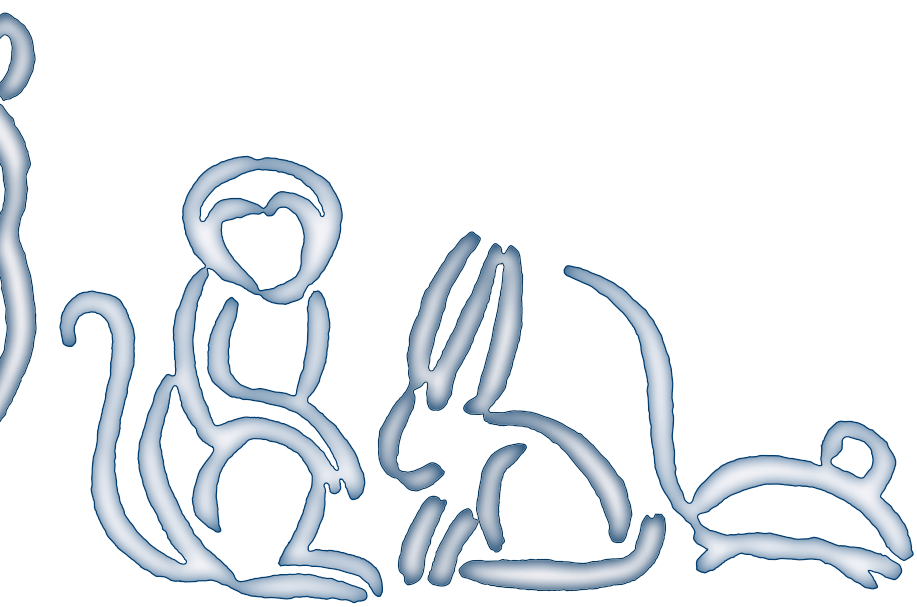

Preface

This 2015 reprint of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) is available in both printed and electronic formats. The electronic version may be found on the Office of Laboratory Animal Welfare (OLAW) website at OLAW.nih.gov and includes hyperlinks to selected documents referred to in the text.

The 2015 reprint of the PHS Policy reflects the following changes from the 2002 reprint: (1) On January 1, 2012, OLAW adopted the *Guide for the Care and Use of Laboratory Animals:* Eighth Edition (*Guide*), an update of the 1996 Seventh Edition, released by the National Academy of Sciences Institute for Laboratory Animal Research (ILAR) in 2011. Institutions with PHS Animal Welfare Assurances implemented the Eighth Edition of the *Guide* during 2012. (2) On February 26, 2013, the American Veterinary Medical Association (AVMA) Panel on Euthanasia released the AVMA Guidelines for the Euthanasia of Animals: 2013 Edition (Guidelines). PHS Assured institutions implemented the 2013 AVMA Guidelines during the period from March 1, 2013, to September 1, 2013. (3) The OLAW mail address has been removed and electronic and fax contact information has been provided to facilitate efficient communication and conserve resources. (4) Footnotes 2, 7, 9, 11, and 13 have been modified to require PHS Assured institutions to comply with U.S. Department of Agriculture regulations that are applicable to their programs. (5) A change in format, but not content, was made to PHS Policy IV.B.3. (6) Grammatical corrections were made to reflect current writing standards.

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 (Principles). 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.

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 at olaw@od.nih.gov, or visit the OLAW website at OLAW.nih.gov.

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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, shall establish guidelines for the following:

"(1) The proper care of animals to be used in biomedical and behavioral research.

"(2) The proper treatment of animals while being used in such research. Guidelines under this paragraph shall require—

"(A) the appropriate use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia for animals in such research; and

"(B) appropriate pre-surgical and post-surgical veterinary medical and nursing care for animals in such research.

Such guidelines shall not be construed to prescribe methods of research.

"(3) The organization and operation of animal care committees in accordance with subsection (b).

"(b) (1) Guidelines of the Secretary under subsection (a)(3) shall require animal care committees at each entity which conducts biomedical and behavioral research with funds provided under this Act (including the National Institutes of Health and the national research institutes) to assure compliance with the guidelines established under subsection (a).

"(2) Each animal care committee shall be appointed by the chief executive officer of the entity for which the committee is established, shall be composed of not fewer than three members, and shall include at least one individual who has no association with such entity and at least one doctor of veterinary medicine.

"(3) Each animal care committee of a research entity shall—

"(A) review the care and treatment of animals in all animal study areas and facilities of the research entity at least semiannually to evaluate compliance with applicable guidelines established under subsection (a) for appropriate animal care and treatment;

"(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.

Reports filed under subparagraph (C) shall include any minority views filed by members of the committee.

"(c) The Director of NIH shall require each applicant for a grant, contract, or cooperative agreement involving research on animals which is administered by the National Institutes of Health or any national research institute to include in its application or contract proposal, submitted after the expiration of the twelve-month period beginning on the date of enactment of this section—

"(1) assurances satisfactory to the Director of NIH that—

"(A) the applicant meets the requirements of the guidelines established under paragraphs (1) and (2) of subsection (a) and has an animal care committee which meets the requirements of subsection (b); and

"(B) scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the applicant have available to them instruction or training in the humane practice of animal maintenance and experimentation, and the concept, availability, and use of research or testing methods that limit the use of animals or limit animal distress; and

"(2) a statement of the reasons for the use of animals in the research to be conducted with funds provided under such grant or contract.

Notwithstanding subsection (a)(2) of section 553 of title 5, United States Code, regulations under this subsection shall be promulgated in accordance with the notice and comment requirements of such section.

"(d) If the Director of NIH determines that—

"(1) the conditions of animal care, treatment, or use in an entity which is receiving a grant, contract, or cooperative agreement involving research on animals under this title do not meet applicable guidelines established under subsection (a);

"(2) the entity has been notified by the Director of NIH of such determination and has been given a reasonable opportunity to take corrective action; and

"(3) no action has been taken by the entity to correct such conditions;

the Director of NIH shall suspend or revoke such grant or contract under such conditions as the Director determines appropriate.

"(e) No guideline or regulation promulgated under subsection (a) or (c) may require a research entity to disclose publicly trade secrets or commercial or financial information which is privileged or confidential."

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 procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible Institutional Official shall ensure that these principles are adhered to:

I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et seq.) and other applicable Federal laws, guidelines, and policies.*

II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.

III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and *in vitro* biological systems should be considered.

IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.

V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.

* For guidance throughout these Principles, the reader is referred to the *Guide for the Care and Use of Laboratory Animals* prepared by the Institute for Laboratory Animal Research, National Academy of Sciences.

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.*

* Published in the *Federal Register*, May 20, 1985, Vol. 50, No. 97, by the Office of Science and Technology Policy [FR Doc. 85-12059].

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 shall 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 that 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 with 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 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.

D. Animal Welfare Assurance or Assurance – The documentation from an institution assuring institutional compliance with this Policy.

E. Guide – *Guide for the Care and Use of Laboratory Animals:* Eighth Edition, National Academy Press, 2011, Washington, D.C., 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 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.

H. Public Health Service – The Public Health Service, or the PHS, includes the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration.

I. Quorum – A majority of the members of the Institutional Animal Care and Use Committee (IACUC).

IV. Implementation by Institutions

A. Animal Welfare Assurance

No activity involving animals may be conducted or 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. Assurances shall be submitted to the Office of Laboratory Animal Welfare (OLAW), Office of the Director, National Institutes of Health (NIH).[1] The Assurance shall be signed by the Institutional Official. OLAW will provide the 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 OLAW to determine the adequacy of the institution's proposed program for the care and use of animals in PHS-conducted or supported activities. On the basis of this evaluation, OLAW 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 OLAW. OLAW 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-conducted or 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-conducted or 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.[2] 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;

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[1] Assurances should be sent to OLAW, NIH, by e-mail to olawdoa@mail.nih.gov or by fax to 301-451-5672.

[2] 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 applicable USDA regulations is an absolute requirement of this Policy.

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 that 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 the 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 are appropriate and humane in accordance with this Policy. However, each institution may identify the committee by whatever name it chooses.

[4] As of the 2015 revision of this Policy, the only accrediting body recognized by the PHS is 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. These programs and facilities 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 will be 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

a. The Chief Executive Officer shall appoint an 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 no fewer 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 (e.g., ethicist, lawyer, and 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 fewer than five members.

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[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-conducted or supported activities:

1. review at least once every six months the institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation;[7]
2. inspect at least once every six months all of the institution's animal facilities (including satellite facilities) using the *Guide* as a basis for evaluation;
3. prepare reports of the IACUC evaluations conducted as required by IV.B.1. and 2. of this Policy, and submit the reports to the Institutional Official;[8]

   (The reports must meet the following criteria:

   a. The reports shall be updated at least once every six months upon completion of the required semiannual evaluations.

   b. The reports shall be maintained by the institution and made available to OLAW upon request.

   c. The reports must contain a description of the nature and extent of the institution's adherence to the *Guide* and this Policy and must identify specifically any departures from the provisions of the *Guide* and this Policy, and must state the reasons for each departure.

   d. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one that, consistent with this Policy, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency.

   e. If some or all of the institution's facilities are accredited by AAALAC or another accrediting body recognized by the PHS, the report should identify those facilities as such.)

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[7] 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 USDA under the Animal Welfare Act. The *Guide* may differ from USDA regulations in some respects. Compliance with applicable USDA regulations is an absolute requirement of this Policy.

[8] The 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 assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report.

4. review concerns involving the care and use of animals at the institution;
5. make recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training;
6. review and approve, require modifications in (to secure approval), or withhold approval of 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.

C. Review of PHS-Conducted or Supported Research Projects

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.[9] 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.

[9] 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 USDA under the Animal Welfare Act. The *Guide* may differ from USDA regulations in some respects. Compliance with applicable USDA regulations is an absolute requirement of this Policy.

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 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, unless a deviation is justified for scientific reasons in writing by the investigator.[10]

2. Prior to the review, each IACUC member shall be provided with a list of proposed research projects to be reviewed. Written descriptions of research projects that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, full committee review of those research projects. 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 research projects and have the authority to approve, require modifications in (to secure approval), or request full committee review of those research projects. If full committee review is requested, approval of those research projects 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 a research project 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.

[10] AVMA Guidelines for the Euthanasia of Animals: 2013 Edition or succeeding revised editions. Available at https://www.avma.org/KB/Policies/Documents/euthanasia.pdf.

3. The IACUC may invite consultants to assist with the review of complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.

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 which 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.

[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 USDA under the Animal Welfare Act. The *Guide* may differ from USDA regulations in some respects. Compliance with applicable USDA regulations is an absolute requirement of this Policy.

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

1. All Institutions

Applications and proposals (competing and noncompeting) for awards submitted to the 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 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.

Noncompeting 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 noncompeting) covered by this Policy from institutions that 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 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.

3. Institutions That Do Not Have an Approved Assurance

For applications and proposals covered by this Policy from institutions that do not have an approved Assurance on file with OLAW, the signature of the official signing for the applicant organization shall constitute a declaration that the institution will submit an Assurance when requested 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 that 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, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld;
    d. records of semiannual IACUC reports and recommendations (including minority views) 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 completion of the activity. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

F. Reporting Requirements

1. At least once every 12 months, the IACUC, through the Institutional Official, shall report in writing to OLAW:
    a. any change in the institution's program or facilities that would place the institution in a different category than specified in its Assurance (see IV.A.2. of this Policy);

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

c. any changes in the IACUC membership;[12] and

d. notice of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities and submitted the evaluations to the Institutional Official.

2. At least once every 12 months, the IACUC, at an institution which has no changes to report as specified in IV.F.1.a.-c. of this Policy, shall report to OLAW in writing, through the Institutional Official, that there are no changes and shall inform OLAW of the dates of the required IACUC evaluations and submissions to the Institutional Official.

3. The IACUC, through the Institutional Official, shall promptly provide OLAW 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*;[13] or

   c. any suspension of an activity by the IACUC.

4. Reports filed under IV.F. of this Policy shall include any minority views filed by members of the IACUC.

V. Implementation by the PHS

A. Responsibilities of 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;

[12] Institutions may, at their discretion, represent the names of the 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.

[13] 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 USDA under the Animal Welfare Act. The *Guide* may differ from USDA regulations in some respects. Compliance with applicable USDA regulations is an absolute requirement of this Policy.

2. distribute to Scientific Review Administrators 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. 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 unless 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 or institutions before an award is made. No award shall be made until all required Assurances have been submitted by the institution or institutions and approved by OLAW, and the institution or institutions 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 advisors, which may include a site visit, to assess the adequacy or accuracy of the institution's compliance or expressed compliance with this Policy.

D. Waiver

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

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