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Last updated February 16, 2001

# United States Department of Agriculture

## Research, Education, and Economics

### ARS \_ CSREES \_ ERS \_ NASS

#### *Policies and Procedures*

- [Number 130.4 - Animal Care and Use Committee](#)
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#### Number 130.4 - Animal Care and Use Committee

This document is available at <http://www.afm.ars.usda.gov/ppweb/>

Title: Animal Care and Use Committee

Number: 130.4

Date: 8/29/90

Originating Office: Office of the Deputy Administrator, National Program Staff

This Replaces: Remove AM 130-4 Dated 6/1/77

Distribution: Headquarters, Areas, and Locations

This Directive states policy, responsibilities, committee membership, committee procedures, including reporting requirements for IACUCs.

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## 1. Reference

For definitions of terms, regulations, animal coverage, and standards of care and use, see DIRECTIVE 635.1, Humane Animal Care and Use.

## 2. Summary

The amended Animal Welfare Act (AWA) regulations contained in 9 CFR Part 2, Subpart 2C, Section 2.37 (see Exhibit 1) require each Federal research facility that uses animals to establish an Institutional Animal Care and Use Committee (IACUC). Locations that receive extramural funds from the Public Health Service (PHS) for studies that use animals in biomedical research and testing require an IACUC. The specific requirements set forth by the AWA and PHS Policy are not identical.

It is ARS Policy for (a) all ARS Locations using ARS funds, personnel, or physical resources; (b) all non-ARS locations using either ARS funds, personnel or animals; or (c) ARS personnel using funds from non-ARS sources and engaging in research and testing that use vertebrate animals to have an IACUC. Although AWA legislation specifically excludes from AWA overview farm animals used or intended for use as food or fiber, or when used or intended for use in agricultural research, it is ARS Policy to include overview of all ARS vertebrate animals by IACUCs at ARS Locations or at non-ARS locations. It is also ARS Policy to include overview by ARS IACUCs of non-ARS animals at ARS Locations or non-ARS locations using either ARS funds or personnel.

The ARS Policy described herein fulfills the requirements of both the AWA and PHS Policy.

This Directive states policy, responsibilities, committee membership, committee procedures, including reporting requirements for IACUCs.

## 3. Abbreviations

AALAS - American Association for Laboratory Animal Science

AD - Area Director

Ag Guide - Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching

APHIS- Animal and Plant Health Inspection Service

AWA - Animal Welfare Act

CD - Center Director

CAD - Contracting and Assistance Division

CRIS - Current Research Information System

CFR - Code of Federal Regulations

IACUC- Institutional Animal Care and Use Committee

LERB - Labor and Employee Relations Branch, Personnel Division, ARS  
NIH - National Institutes of Health  
NIH Guide - NIH Guide for the Care and Use of Laboratory Animals  
NPS - National Program Staff  
OPRR - Office for the Protection from Research Risks, NIH  
PD - Personnel Division  
PHS - Public Health Service  
PI - Principal Investigator  
PL - Public Law  
REAC - Regulatory Enforcement Animal Care, APHIS  
VS - Veterinary Services, APHIS

## 4. Definitions

Activity. Each unique, related series of procedures done on an animal or group of animals addressed in a single Protocol Form.

Protocol Form. The form that contains descriptions of animal care and use activities for which IACUC approval is requested by the PI. Points which must be addressed in the Protocol Form are described in AWA, 9 CFR, Subpart 2C, Section 2.31[d] (see Exhibit 1).

Cooperator. AB used in this Directive, taken to mean any non-ARS personnel caring for or using any vertebrate animal at an ARS Location.

## 5. Forms

VS Form 18-1, USDA Interstate and International Certificate of Health Examination for Small Animals. See Exhibit 2 for model form. This form and other VS forms can be obtained from Sector Supervisor, REAC, APHIS at the addresses listed.

VS Form 18-5, Record of Dogs and Cats on Hand. See Exhibit 2 for model form.

VS Form 18-6, Record of Disposition of Dogs and Cats. See Exhibit 2 for model form.

APHIS Form 7008 (Replaces Form VS Form 18-8), Inspection of Animal Facilities, Sites or Premises. The numbers on the refer to AWA, Standards section of 9 CFR 3. Obtain forms from REAC/APHIS. See Exhibit 2 for model Form and APHIS addresses.

VS Form 18-23, Annual Report of Research Facilities. Obtain Forms from REAC/APHIS. See Exhibit 2 for model Form and APHIS addresses.

ARS Form 605, Annual Report of Farm Animals Used in Agricultural Research (Exhibit 3).

ARS Form 606, IACUC Membership (Exhibit 3).

## 6. Authorities

- Laboratory Animal Welfare Act of 1966 (PL 89-544) as amended by the Animal Welfare Act of 1970 (PL 91-579); 1976 (PL 94-279); and 1985 (PL 99-198).
- 9 CFR 1, 2 (Subpart 2C), and 3.
- Health Research Extension Act, Section 495 (Animals in Research) (PL 99-158). PHS Policy on Humane Care and Use of Laboratory Animals as revised 1986 and the NIH Guide for the Care and Use of Laboratory Animals, revised 1985 (NIH Publication 86-23).

- Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, First Edition 1988 (Chapters 5-11). Also referred to as Ag Guide in this Directive.
- Interagency Research Animal Committee's U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training, Federal Register, May 20, 1985, V. 50, No. 97 (Exhibit 4).

## 7. Coverage

Use of all vertebrate animals for any purpose used at either any ARS Location, regardless of source of funds, or at another location using ARS funds or ARS personnel regardless of source of funds.

## 8. Policy

It is ARS policy:

To include all vertebrate animals used at either any ARS Location, regardless of source of funds, or at another location using ARS funds or ARS personnel regardless of source of funds under the IACUC overview provisions outlined in 9 CFR Part 2C (AWA). Further, the constitution of these IACUCs will conform to minimum membership and distribution characteristics stated in PHS Policy (i.e., at least five members). This statement formalizes Memoranda from ARS Administrator 1986, 1987, 1988, and 1989.

That all ARS Locations using vertebrate animals or other locations using ARS animals, personnel or funds for supporting any vertebrate animal use and also receive funds from any PHS agency, conform to the assurance requirements set out in PHS Policy Guidelines.

## 9. Responsibilities

The Administrator through the NPS administers the program and assures regulations and standards are enforced.

The AD's assure:

- IACUCs are established where required. b Regulations and standards are enforced.
- Members and chairpeople of IACUCs are appointed.
- That noncompliances with ARS Policy, AWA, NIH Guide, and Ag Guide are corrected/resolved in a timely manner. Further, when warranted, cases involving animal abuse should be referred to LERB (when ARS employees are involved) or to CAD (when cooperator employees are involved) for a determination of the appropriateness of disciplinary or remedial actions.
- Review of reports to assure regulations, standards, and policies are enforced and then certify accuracy of reports. Transmit annual reports to REAC/APHIS (see Exhibit 2 for addresses), OPRR/NIH (when necessary), and NPS.
- Provision of consultation and guidance deemed necessary under AWA and ARS Policy.
- Upon request of APHIS representative, information required under the AWA is furnished. For ARS Locations receiving PHS funds, upon request of OPRR/NIH representative, information required under PHS Policy is furnished.
- Deficiencies in animal facilities are corrected promptly.

The IACUC:

- Reviews and approves or disapproves all proposed activities for use of animal subjects (commonly known as "Protocol Review-); maintains a record of these reviews and also transmits the results of such reviews to the PI and Location's highest management official (if other than AD). This review shall conform to the standards set forth in AWA, 9 CFR 2C, Section 2.31.

NOTE: Proposed animal use activities that have been approved by the IACUC may be subject to further review

by CD or AD or NPS. However, these officials cannot approve sections of a proposal related to the care and use of animals if they have not been approved previously by the IACUC.

- Monitors animal use activities through Protocol Form review and facility inspections to assure that once an experimental procedure has been approved, no substantial change is made unless a formal request (amended Protocol Form) with appropriate justification is submitted to the IACUC and approved.
- Conducts annual review of all activities for use of animal subjects that exceed periods longer than 1 year and approve continuation or suspend approval. File maintenance and transmission of results of Protocol Form review are as stipulated in I.3.a (above).
- At irregular intervals, dictated by complaint of nonconformance to the stipulations in an approved activity or request from PI for approval of change in an approved activity, reviews an animal use activity. All requested changes must be approved by the IACUC before the activity proceeds. Investigations of complaints are addressed in paragraph I.3.e (below). File maintenance and transmission of results of review are as stipulated above.
- Promptly investigate all complaints concerning abuse of animals, nonconformance with stipulations of an approved activity, or failure to comply with provisions of the AWA, NIH Guide, Ag Guide, and ARS Directives concerning care and use of animals. If warranted after investigation of complaints, recommend to the AD a course of corrective action including, but not limited to, referral to LERB (when ARS employees are involved) or CAD (when cooperator employees are involved) to determine whether formal investigation concerning possible disciplinary action is warranted regarding any employee or cooperator found to have abused animals.
- Review, at least every 6 months, the location's program for humane care and use of animals using AWA 9 CFR Subpart 2C, the NIH Guide, and the Ag Guide as bases for evaluation.
- Inspect, at least every 6 months, all of the locations' and tenant agencies' animal facilities, including satellite facilities and other study areas (defined as "any building, room, area, enclosure, or other containment outside of the centrally designated or managed area") in which animals are held for more than 12 hours. The NIH Guide, Ag Guide, and AWA 9 CFR Subpart 2C are used as bases for evaluation.
- Prepare semiannual reports of IACUC evaluations for the AD. These reports must contain a description of any major deviations (and reasons for such deviations) from the requirements outlined in AWA 9 CFR Subpart 2C, PHS Policy (where relevant) and the Ag Guide. In cases of major deviations, the IACUC Chair and attending veterinarian should immediately suspend the problem activity, report to AD, and request immediate correction of the problem or, if not possible, terminate the problem-causing activity.
- In consultation with PD, procure, develop, or recommend to AD sources of training in humane care and use of animals and regulatory overview for ARS employees, including those not directly involved with animal care and use. The attending veterinarian member of the IACUC has the specific responsibility for assuring that animal surgery, pre- and post-surgical care, and appropriate methods of euthanasia comply with currently accepted veterinary practices.
- Maintain files documenting IACUC membership, animal facility inspections, reports to AD, Protocol Form reviews, and IACUC meeting minutes for at least 3 years.

## 10. Committee Membership

Consists of at least:

One Doctor of Veterinary Medicine, with training or experience with the care of the species in residence at the Location and who has direct or delegated program responsibility for activities involving animals at the Location.

One scientist experienced, and currently active, in research involving animals.

One member whose primary concerns are in a nonscientific area (e.g. ethicist, attorney, business person, clergy etc.).

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 or a person who is affiliated with the institution.

NOTE: Furthermore, an individual who meets the requirements of more than one of the above categories may fulfill more than one requirement. However, no IACUC may have fewer than 5 members.

It is strongly recommended that all ARS IACUCs include, in addition to a senior scientist, an animal technician or caretaker.

Rotation of IACUC membership is encouraged.

## **11. IACUC Officers and Duties**

### Chairperson:

- Calls meetings as often as required for timely reviews of animal care and use protocol forms and other business. Meetings must be called at least semiannually.
- Assures that IACUC activities meet regulatory requirements. Develops and submits reports to AD.
- On own initiative, or upon request of the IACUC, makes recommendations to AD on any aspect of humane care and use of animals.
- Promptly leads investigation of allegations of animal abuse. Reports results of investigations to the AD and, if warranted, recommends a course of corrective action including, but not limited to, referral to LERB to determine whether formal investigation concerning possible disciplinary action is warranted regarding any employee found to have abused animals or to CAD concerning a cooperator found to have abused animals. Maintains the official IACUC file.

### Secretary:

- Records minutes at IACUC meetings.
- Prepares the reports developed by the IACUC chairperson.
- Maintains file of IACUC members and any secondary files agreed upon by the ARS Location's management
- Sends out IACUC meeting notices, draft minutes, and meeting agendas to IACUC members in a timely manner.

## **12. IACUC Meetings**

- Held at least semiannually for business other than Protocol Form review. Meetings must be held after each semiannual facility inspection so that the results can be reviewed by a quorum of the IACUC members and recommendations concerning those inspections developed for transmission to the AD.
- Protocol Form review meetings must be held with a frequency that assures timely transmission of results of the review to the PI. The AWA allows Protocol Form review by a subcommittee as long as: (a) all members of the IACUC receive a complete list of all Protocol Forms to be reviewed and (b) any member of the IACUC can request review of the animal care and use Protocol Forms by the full IACUC. Any minority votes on a Protocol Form review must be recorded along with the grounds for the vote.
- Written records of IACUC meetings must be made and kept for 3 years.

## **13. Reports**

### Attending Veterinarian

On or before November 15 of each year, prepare original and three copies of VS Forms 18-5, 18-6, and 18-23 and ARS 605 covering the previous fiscal year ending September 30 and transmit the signed documents to IACUC secretary.

### Secretary IACUC

On or before November 15 of each year, prepare original and three copies of report of activities of IACUC and also prepare IACUC membership form (ARS 606).

Only for locations that receive PHS funds and, therefore, have filed an Assurance with OPRR/NIH~ annually on or before December 1, prepare original and three copies of the annual report stipulated by PHS Policy.

Distribute documents: Original and two copies to AD.

Retain documents: Retain one copy for file.

NOTE: Discard copies after 3 years.

## AD

When documents are received, review for accuracy and compliance with ARS, AWA, and PHS policy. Accuracy is certified by AD signature.

Distribute documents:

- Original certified copy of VS Form 18-23 to Sector Supervisor, REAC, APHIS (See Exhibit 2 for addresses).
- Original certified copy of PHS Annual Assurance Report to OPRR/NIH, Building 31, Room 5B59, Bethesda, Maryland 20892.
- One certified copy of the reports listed in M1, M2 [a list of all members of the IACUC along with their offices (if any) in the IACUC, highest academic degree, inclusive term of membership on the IACUC, official ARS title, and complete mailing address and telephone number (including area code)] and M3 (for Locations that receive PHS funds) to NPS Animal Care Office, BARC-West, Beltsville, Maryland 20705.

Retain:

One certified copy for file.

NOTE: Discard copies after 3 years.

**R. D. PLOWMAN**  
**Administrator**

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**Number 635.1 - Humane Animal Care and Use** This document is available at <http://www.afm.ars.usda.gov/ppweb/>

**Title:** Humane Animal Care and Use

**Number:** 635.1

**Date:** 8/29/90

**Originating Office:** Office of the Deputy Administrator National Program Staff

**This Replaces:** AM 535 dated 6/1/77

**Distribution:** ARS Headquarters, Areas, and Locations

This Directive states:

ARS Policy; lists coverage of animals under Public Laws, Polices and ARS practices; and assigns responsibilities for assuring humane animal care and use.

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### 1. Reference

For additional information see DIRECTIVE 130.4, Animal Care and Use Committee.

### 2. Abbreviations

AALAS - American Association for Laboratory Animal Science

AD - Area Director

AV - Attending Veterinarian

AWA - Animal Welfare Act

APHIS - Animal and Plant Health Inspection Service, USDA

CFR - Code of Federal Regulations

Ag Guide - Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching

IACUC - Institutional Animal Care and Use Committee

LERB - Labor and Employee Relations Branch, Personnel

PL - Public Law

REAC - Regulatory Enforcement Animal Care, APHIS

RL - Research Leader (ARS)

SY - Research Scientist (ARS)

VS - Veterinary Services, APHIS

### 3. Definition

Cooperator. As used in this Directive, taken to mean any non-ARS personnel caring for or using any vertebrate animal at an ARS Location.

### 4. Coverage

#### 1. [ARS Policy](#):

- a. [Includes](#): All vertebrate animals in all ARS Locations, or other locations in which ARS funds or ARS personnel are involved.

b. Excludes: Invertebrate animals.

## 2. AWA:

a. Includes: Any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warmblooded animal, used or intended for use in research, teaching, testing, experimentation, or exhibition purposes, or as a pet.

b. Excludes: Birds, rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research, and horses and other farm animals, such as, but not limited to livestock and **poultry used** or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.

## 3. PHS Policy:

a. Includes: Any animal (including farm animals) used in biomedical research and testing funded by a PHS Agency or in any institution that receives funds from a PHS Agency.

b. Excludes: Livestock and poultry used or intended for use that also is excluded from coverage by the AWA.

## 4. Ag Guide:

a. Includes: Livestock and poultry used in agricultural research and teaching.

b. Excludes: Animals covered by AWA or PHS.

## 5. **Authorities**

- Laboratory Animal Welfare Act of 1966 as amended by the Animal Welfare Act of 1970, 1976 and 1985.
- 9 CFR 11.2 (Subpart 20, and 3).
- U.S. PHS Policy on Humane Care and Use of Laboratory Animals, 1986 revision.
- NIH Guide for the Care and Use of Laboratory Animals, 1985 revision (NIH Publication No. 86-23).
- Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, First Edition March, 1988.

## 6. **Policy**

It is ARS policy to assure that all ARS research animals are treated humanely. Allegations of animal abuse must be reported promptly, in writing, to the Chairperson, IACUC, and the AD. It is ARS Policy to assure that all ARS research facilities and other facilities using ARS animals, funds or personnel for any animal use comply with the following:

### 1. The AWA, for animals used in biomedical research, testing or teaching and covered by the AWA including:

- a. The AWA, its amendments, regulations, and standards concerning procurement, transportation, care, handling, and treatment of animals, training of personnel, and employee health programs (Exhibit 1).
- b. Requirement to maintain IACUCs in all ARS Locations that have animals covered by the AWA (except that ARS requires a minimum of five members whereas AWA requires a minimum of three). See also Directive 130.4, Animal Care and Use Committee.

- c. Assurance that animals not covered under the AWA receive the same level of humane animal care and treatment.
- d. Review, and, if warranted, investigate concerns involving care and use of animals resulting from complaints or reports of noncompliance.

2. PHS Policy, for ARS facilities receiving funds from any PHS agency including:

- a. "PHS Policy, and also NIH Guide concerning procurement, transportation, care, handling, and treatment of animals, training of personnel, and employee health programs (Exhibit 2).
- b. Maintain IACUCs that comply with PHS Policy in all ARS Locations that use animals. Note that ARS and PHS Policy concerning IACUC size and composition are identical. See also Directive 130.4, Animal Care and Use Committee.
- c. Assurance that animals not covered under PHS Policy receive the same level of humane animal care and treatment.

3. Ag Guide, for ARS facilities or facilities receiving ARS funds and using farm animals for any purpose with the following stipulations:

Ag Guide chapters 5-11 outlining appropriate husbandry practices for various species of farm animals (Exhibit 3).

## **7. Licensing and Registration**

1. Not required for Federal agencies under the AWA.
2. Filing of an annual PHS Assurance with OPRR/NIH is required for all ARS Locations that receive funds from any PHS agency. Many other public and private funding entities also require filing of a PHS Assurance as a condition of grant/contract completion.

## **8. Responsibilities**

1. The Administrator, where applicable, through the NPS, assures compliance with ANA, PHS Policy and NIH Guide, Ag Guide, and ARS Policy concerning humane care and use of all vertebrate \1-1/ animals.

2. AD's assure:

- a. IACUCs are established where required and maintained in operation.
- b. IACUC members and Chairpeople are appointed and function according to Directive 130.4, Animal Care and Use Committee.
- c. That all employees who work with animals are appropriately trained.
- d. Regulations, standards, and policies are enforced.
- e. Reporting requirements for AWA, PHS Policy (where applicable), and ARS are met in a timely manner.
- f. Deficiencies, including those involving physical facilities, are corrected promptly.
- g. Procurement of all vertebrate animals in Areas/Centers/Locations is covered by an IACUC approval for the stipulated number of animals.
- h. Consultation to IACUC, Attending Veterinarians, and/or other employees concerning animal care and welfare is provided.
- i. That upon request of APHIS representatives, information required under the AWA is furnished.
- j. That, if needed, assistance is requested from APHIS and/or OPRR/NIH concerning attainment of policy goals.

- k. Funds and time are provided for employees to receive training required under the AWA.
- l. Reported noncompliances with ARS Policy, the AWA and/or PHS Policy are investigated promptly and resolved.
- m. That prompt disciplinary action is taken regarding any employee or cooperator found to have abused animals.

3. Area/Center/Location Procurement Officer and Area/Center Location Property Office will assure that all orders for acquisition and disposition of all vertebrate animals comply with the AWA and ARS Directives concerning approved sources, and assurance that appropriate documentation accompanies all acquisitions and dispositions of animals.

4. RLs/SYs assure:

- a. Acquisition of all animals comply with the AWA and ARS Policy.
- b. Recordkeeping complies with the AWA, including the special recordkeeping required for dogs and cats that is described in Subpart 2C, Section 2.35.
- c. Compliance with all special requirements concerning dogs and cats (Directive 130.4, Animal Care and Use Committee) that are delegated to RLs/SYs.
- d. Dogs and cats obtained from sources other than dealers, exhibitors, and exempt persons are held for at least 5 full days before they are used.
- e. All animals held or used for any purpose are covered by IACUC approval.
- f. Recordkeeping provisions of the AWA, Subpart 2C, Section 2.35 concerning dogs and cats are followed and forms/records are forwarded to the appropriate Area IACUC (the official Area Record).
- g. They personally, as well as their technicians, caretakers, students, and others are aware of and follow regulations and standards for humane care of animals used in any manner by them and/or their subordinates.
- h. Any inadequacies in care, handling, or environmental conditions concerning animals are promptly reported and corrected.
- i. Maintenance of training on regulatory requirements and humane care and use of animals.
- j. Disposition of all healthy surplus animals comply with ARS property disposal procedures for disposition of surplus government animals. In addition, disposition of all dogs and cats also must comply with the AWA concerning recordkeeping (Subpart 2C, Section 2.35), euthanasia, sale, or transportation.

5. Attending Veterinarian:

- a. Serves on the IACUC
- b. Assures that:
  - i. All vertebrate animals receive adequate veterinary care in compliance with the AWA, NIH Guide, and Ag Guide.
  - ii. Guidance is provided to appropriate research and care personnel concerning, including but not limited to, care and use of animals regarding humane handling, immobilization, anesthesia, analgesia, euthanasia, tranquilization, as well as pre-and post-procedural care in accordance with established veterinary and nursing procedures and the AWA.
  - iii. VS Form 18-23 covering the previous fiscal year ending September 30 is accurately completed, receives concurrence by IACUC, and forwarded to AD for transmission to REAC/APHIS and NPS/ARS in a timely manner.
  - iv. ARS Form 605 covering the previous fiscal year ending September 30 is accurately completed, receives concurrence by IACUC, and forwarded to AD for transmission to NPS/ARS in a timely manner.
  - v. Animal caretakers receive an adequate level of training to provide optimum care of animals.
  - vi. Chairperson, IACUC, RL, Center Director, and AD are promptly notified about all failures to comply with provisions of AWA, NIH Guide, and Ag Guide concerning regulations and standards.
  - vii. Knowledge of new veterinary medical developments and regulatory requirements is maintained through a continuing program of training.

6. Consulting Veterinarian assume same responsibilities as attending veterinarian.

## 7. Animal Caretakers assure:

- a. All animals under their responsibility receive care consistent with the AWA, NIH Guide, and Ag Guide on a daily basis, except for free ranging animals where Location IACUCs set the appropriate frequency.
- b. All management and environmental requirements for animals are met in a timely manner.
- c. Maintenance of current knowledge of all aspects of care for the species in their charge through a continuing program of training.
- d. That during the first year of employment as animal caretaker, they take a course leading to certification given by AALAS (for laboratory animal caretakers) or by another organization/institution (for caretakers of species for which AALAS training is inappropriate). This course must contain training in current animal care practices and regulatory requirements relevant to the species in use. Lists of appropriate training courses leading to employee certification may be obtained from the IACUC. Employee certifications will be updated periodically to assure that they reflect current animal care practices, regulatory requirements, and relevance to the species being cared for.
- e. On or before the first year of employment as animal caretaker, receive certification in the appropriate training course (described in H.7.d above). Failure to meet the certification requirement within a year after entering on duty will be grounds for dismissal.

8. IACUCs will fulfill all of the requirements in Directive 130.4, Animal Care and Use Committee.

**R. D. PLOWMAN**  
**Administrator**

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**Last updated February 22, 2001**

# Department of Defense

**DIRECTIVE**  
**April 17, 1995**  
**NUMBER 3216.1**

## Use of Laboratory Animals in DoD Programs

This document is available at [http://www.army.mil/usapa/epubs/pdf/r40\\_33.pdf](http://www.army.mil/usapa/epubs/pdf/r40_33.pdf)

### References:

(a) DoD Directive 3216.1, "Use of Animals in DoD Programs , " February 1, 1982 (hereby canceled)

(b) Title 9, Code of Federal Regulations, "Animals and Animal Products, " Chapter 1, Subchapter A, "Animal Welfare, " Parts 1, 2, and 3

(c) Public Law 101-511, Department of Defense Appropriations Act for Fiscal Year 1991, Section 8019, Title 10 United States Code, Section 2241

(d) Sections 2131 through 2156 of Title 7, United States Code "The Laboratory Animal Welfare Act of 1966, " as amended

(e) through (f) , see enclosure 1.

### **A. REISSUANCE AND PURPOSE**

1. Reissues reference (a) to update policy governing activities using animals within the Department of Defense.
2. Designates the Secretary of the Army as the DoD Executive Agent to develop and issue Service regulations to implement this Directive.

### **B. APPLICABILITY**

This Directive applies to the Office of the Secretary of Defense, the Military Departments, the Uniformed Services University of the Health Sciences, and the Defense Agencies (hereafter referred to collectively as "DoD Components") that perform or sponsor activities using animals.

### **C. DEFINITIONS**

Terms used in this Directive are defined in enclosure 2.

### **D. DoD POLICY**

1. Federal statutes, regulations, and publications that provide national standards and guidance for the acquisition, transportation, housing, control, maintenance, handling, protection, treatment, care, use, and disposal of animals shall be applicable to all activities using animals. A summary of the applicable documents cited as references is in enclosure 3.
2. Animals shall be legally obtained from suppliers licensed by the U.S. Department of Agriculture (USDA) in accordance with reference (b) unless specifically exempted from the licensing requirements stated in reference (b) .
3. DoD organizations or facilities maintaining animals for use in research, testing or training shall apply for accreditation by the American Association for Accreditation of Laboratory Animal Care (AAALAC) .
4. Alternative methods to animal species shall be considered, whenever possible, if such alternatives produce scientifically valid or equivalent results to attain the research testing and training objectives.
5. The purchase or use of dogs, cats, or nonhuman primates in research conducted for developing biological, chemical or nuclear weapons is prohibited.
6. The purchase or use of dogs, cats, or nonhuman primates for inflicting wounds from any type of weapon(s) to conduct training in surgical or other medical treatment procedures is prohibited. (reference (c)).
7. DoD organizations or facilities wishing to hold training programs using animals, such as advanced trauma life support (ATLS) training programs, shall have the training protocol reviewed and approved by a duly constituted Institutional Animal Care and Use Committee (IACUC) in accordance with references (d) u and (e) and paragraph D.8. of this Directive to ensure the humane use of animals. DoD organizations or facilities conducting ATLS training that require housing of animals for short periods of time shall ensure adequate care and shall have the animal housing facilities inspected and approved by a veterinarian prior to receipt of the animals.
8. All proposals or protocols for animal experiments or demonstrations in RDT&E, clinical investigation, instructional, or training programs conducted or sponsored by a DoD organization or facility shall be reviewed and approved by a duly constituted IACUC composed of a minimum of five members. There shall be at least one non-scientific member on each IACUC. In addition, there also shall be a member who represents the general community interest and is non-affiliated with the facility sponsoring IACUC. The non-affiliated and the non-scientific membership can be filled by the same person. To ensure community representation at each meeting and inspection, an alternate to the non-affiliated member shall be designated for IACUCS having a single non-affiliated membership. Since the DoD IACUCS perform a Government function in an approval process and do not serve merely as an advisory body, the non-affiliated and the non scientific member(s) to DoD IACUCS shall either be a Federal employee, with demonstrated commitment to the community or a consultant consistent with the requirements established by reference (f) .
9. A headquarters-level administrative review shall be conducted for proposals involving the use of nonhuman primates conducted or sponsored by subordinate activities of the DoD Component for conformance with all applicable Federal regulations and policies. A DoD component may delegate this responsibility to another DoD component for purposes of efficiency and consolidation of functional offices.
10. The DoD Components shall coordinate and cooperate in the transfer of Government-owned nonhuman primates between facilities to maximize conservation and proper utilization.
11. Proposals intending to use chimpanzees must be further reviewed and approved by the Interagency Animal Model Committee, which coordinates national priorities for research utilization of this species.

12. The DoD components that sponsor animal based research, testing, and training under a DoD grant or contract shall ensure that:

- a. all extramural research proposals using live animals shall be administratively reviewed by a DoD veterinarian trained or experienced in laboratory animal science and medicine before grant or contract award.
- b. the most recent USDA inspection reports are provided or obtained for the facility under consideration for a research contract or grant using animals, and that during the term of the award, the most recent USDA inspection reports be reviewed on an annual basis.
- c. a DoD veterinarian trained or experienced in laboratory animal science and medicine shall conduct an initial site visit to evaluate animal care and use programs at contracted facilities conducting DoD-sponsored research using non-human primates, marine mammals, dogs, cats, or proposals deemed to warrant review. The initial site visit shall occur within 6 months of when the facility has taken delivery of the animals under DoD contract or grant award. Any facility receiving a DoD-funded grant or contract for animal based research shall notify the DoD component sponsor and shall have a site inspection within 30 days of notification of loss of AAALAC accreditation for cause, or notification that the facility is under USDA investigation. Site inspections for cause shall evaluate and ensure the adequacy of animal care and use in DoD-sponsored programs, and provide recommendations to the sponsoring DoD component about continued funding support of the research.

13. In the case of differences between the standards of care and use of animals as cited in enclosure 3, the most stringent standard shall apply.

14. Activities covered by this Directive that are performed or sponsored in foreign countries shall be conducted in accordance with applicable U.S. statutory requirements, and regulations and standards of the host country. If differences exist between U.S. and host country regulations or standards, unless prohibited by the host country, the more stringent standard shall apply.

15. While not specifically addressed in this Directive, ceremonial, recreational, and working animals, such as military working dogs, shall be treated in a humane manner.

16. Personnel with complaints of violation of this directive shall report such violations to either of the following members of the organization or facility: IACUC chairperson, attending veterinarian, the facility Commander, or Inspector General. The IACUC shall review and, if warranted, investigate all reports of complaints of animal use or noncompliance with 7 U.S.C. 2131- 2 of reference (d), applicable Directives, and regulations.

## **E. RESPONSIBILITIES**

1. The Director, Defense, Research and Engineering (under the Under Secretary of Defense for Acquisition and Technology) or designee shall:

- a. Issue policy and procedural guidance concerning animal use consistent with all applicable Federal regulations and policies.
- b. Designate a DoD representative to the Interagency Research Animal Committee who is a veterinarian of appropriate rank or grade and experience, and preferably also a diplomate of the American College of Laboratory Animal Medicine.
- c. Establish the Joint Technical Working Group (JTWG) to act as the central advisory committee to the Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee on all matters on the care and use of animals for research, testing, clinical investigation, or training within the Department of Defense. The co-chairpersons of the ASBREM Committee shall designate the chairperson of JTWG.

2. The Heads of the DoD Components shall:

- a. Establish appropriate mechanisms to monitor compliance with this Directive and applicable Federal statutes and regulations.
- b. Establish offices or facilities that shall serve as reviewing or approving authorities of animal use proposals from subordinate activities and extramural facilities proposing research under contract or grant.
- c. Provide members to JTWG as required.
- d. Designate the appropriate office(s) within the DoD Component that shall perform the headquarters level administrative review of proposals requiring the use of non-human primates and shall serve as the office where exemptions under paragraph D.2. above may be approved.
- e. Support, and as necessary, ensure the development of animal care and use training programs for researchers and members of the IACUC, and certification programs for all personnel involved in the care, use, and treatment of animals.

3. The Secretary of the Army shall:

- a. As Executive Agent, develop and issue, in consultation with the other DoD Components, joint Service regulations to implement this Directive.
- b. Designate the Commander, U.S. Army Veterinary Command/Director, DoD Veterinary Services Activity, a Field Operating Agency of the Army, Office of the Surgeon General who shall serve as a consultant to the Assistant Secretary of Defense for Health Affairs and the Director, Defense Research and Engineering for technical and professional matters related to this Directive.

## **F. EFFECTIVE DATE**

This Directive is effective immediately.

Enclosures - 3

1. References
2. Definitions
3. Guidance Documents

John M. Deutch

Deputy Secretary of Defense

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April 17, 1995

3216.1 Enclosure 1

- (e) National Institutes of Health (NIH) Publication No. 86-23, "Guide for the Care and Use of Laboratory Animals", United States Department of Health and Human Services, National Institutes of Health, Revised 1985.
  - (f) Title 5, United States Code, Section 3109.
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Apr 17, 95

## DEFINITION OF TERMS

1. **Animal-** Any dog, cat, non-human primate, guinea pig, hamster, rabbit or any other live vertebrate animal, which is being used or is intended for use for research, training, testing, or experimentation purposes. For this Directive, it includes birds, rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research, training, testing or experimentation purposes. The term excludes animals used for ceremonial or recreational purposes, military working animals, and animals intended for use as livestock and poultry as food or fiber; or, livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.
  2. **Clinical Investigation-** All activities directed towards clinical research conducted principally within medical treatment facilities. The Clinical Investigations program is part of the Defense Health Program of the Assistant Secretary of Defense (Health Affairs) and is supported by Major Force Program 8 (MFP-8) funds.
  3. **Instructional Program-** All educational and training activities, except training of ceremonial and recreational animals and training associated with military working animals or survival skills training.
  4. **Research, Development, Test, and Evaluation-** All activities which form the RDT&E program of the Director, Defense Research and Engineering (DDR&E) and are supported by Major Force Program 6 (MFP-6) funds.
  5. **Alternatives-** Any system or method that covers one or more of the following: replacing or reducing the number of laboratory animals required for an investigation by computer simulation, cell culture techniques, etc; or, refining an existing procedure or technique to minimize the level of stress endured by the animal.
  6. **DoD Sponsored Programs-** All proposals or designs for animal experiments or demonstration in RDT&E, clinical investigation, or instructional programs conducted or funded by grant, award, loan, contract, or cooperative research and development agreement (CRADA).
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Apr 17, 1995  
3216.1 (Encl 3)

## ADDITIONAL FEDERAL STATUTES , REGULATIONS, AND GUIDELINES ON THE USE OF ANIMALS

The following documents provide national standards and guidance for the protection, treatment and use of animals:

- a. **Animal Welfare Act** (Title 7, United States Code, Sections 2131-2158, as amended, and Title 9, Code of Federal Regulations, Parts 1-4, implementing rules and regulations) . Administered by Regulatory Enforcement and Animal Care (REAC), Animal and Plant Health Inspection Service (APHIS) of the Department of Agriculture. Requires licensing of dealers, identification of animals, maintenance of records, submission of reports, establishment of an Institutional Animal Care and Use Committee (IACUC), and compliance with standards for the humane handling, care, treatment, and transportation of animals by dealers and research facilities.
- b. **Endangered Species Act** of 1973 (Title 16, United States Code, Sections 1531-1543, as amended, and Title 50, Code of Federal Regulations, Parts 10-14 and 217-227, implementing rules and regulations) . Provides a program under the U.S. Fish and Wildlife Service, Department of Interior, for conserving threatened and endangered species. Requires import/export - permits, maintenance of records, and submission of reports on the

care and handling of endangered, threatened, and conserved species.

c. **Marine Mammal Protection Act** (Title 16, United States Code, Sections 1361-1384, as amended, and Title 50, Code of Federal Regulations, Parts 10-14 and 216-227, implementing rules and regulations) . Provides a program under the Departments of Commerce (National Marine Fisheries Service) and Interior (U.S. Fish and Wildlife Service) for the protection of marine mammals and marine mammal products. Requires acquisition permits, maintenance of records, submission of reports, and inspections on the care and handling of marine mammals.

d. **Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)** (TIAS 8249, as amended, and Title 50, Code of Federal Regulations, Part 23, implementing rules and regulations) . CITES is a treaty involving 106 signatory nations administered in the United States by the Fish and Wildlife Service of the Department of the Interior. CITES regulates the import and export of imperiled species covered by the treaty but imposes no restrictions or control on interstate shipments.

e. **Lacey Act** (Title 18, United States Code, Section 42, as amended, and Title 50, Code of Federal Regulations, Part 16 and Subpart B, implementing rules and regulations) . A program under the U.S. Fish and Wildlife Service, Department of the Interior. Prohibits the importation of certain wild animals or their eggs if the Secretary of the Interior determines that they are injurious to humans, the interest of agriculture, or other specified national interests.

f. **Guide for the Care and Use of Laboratory Animals**. Public Health Service, National Institutes of Health, NIH Publication No. 86-23, Revised. Provides guidelines for institutional policies, husbandry, requirements, veterinary care, and physical plant requirements for programs involving the care and use of laboratory animals.

g. **Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching**. Published by the Consortium for Developing a Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, 309 West Clark Street, Champaign, IL 61820, March 1988. Provides guidelines for the care and use of the major agricultural animal species in the United States in research and teaching. [Ed. Note: An updated version of this document is now available from the Federation of Animal Science Societies, 1111 North Dunlap Avenue, Savoy, IL 61874 USA, telephone: (217) 356-3182, fax: (217) 398-4119, e-mail: [fass@assoqhq.org](mailto:fass@assoqhq.org)

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Updated March 12, 2002

# **Department of Veterans Affairs**

## **Veterans Health Administration**

**Washington DC 20420**

VHA DIRECTIVE 10-95-031

April 14, 1994

### **DEPARTMENT OF VETERANS AFFAIRS (VA) RESPONSIBILITY FOR VA-OWNED RESEARCH ANIMALS HOUSED IN NON-VA FACILITIES AND NON-VA-OWNED RESEARCH ANIMALS HOUSED IN VA FACILITIES**

**1. PURPOSE:** The purpose of this Veterans Health Administration (VHA) directive is to make explicit the application of provisions of M-3, Part I, Chapter 12, Animal Subjects in Research, to: (a) animals owned by the Department of Veterans Affairs (VA), but housed in non-VA research facilities, and (b) animals housed in VA facilities, but owned by non-VA entities. This directive will be incorporated into M-3, Part I, Chapter 1 by February, 1995.

**2. BACKGROUND:** In 1992, The United States Department of Agriculture (USDA) informed VA that research animals owned by VA but held in non-VA facilities, were subject to VA oversight by the SAS (Subcommittee on Animal Studies (SAS) of the VA medical center Research and Development (R&D) Committee. In response to these expectations, and similar expectations where converse arrangements for housing non-VA animals in VA housing existed, further clarification to avoid duplication of effort was sought with USDA and Office for Protection from Research Risks (OPRR)/National Institutes of Health (NIH). The policies and procedures announced in this directive are designed to meet VA, USDA, and OPRR requirements with respect to oversight of research animal care and use practices in the situations described.

### **3. POLICY**

- VA medical centers, acting through the SAS, are responsible for ensuring the humane care and treatment of vertebrate animals used or intended for use in laboratory research. This responsibility extends not only to animals owned by VA and housed in VA facilities, but also to those: (1) owned by VA, but housed in non-VA research facilities, and those (2) housed in VA research facilities, but owned by non-VA entities.
- The SAS must fulfill the programmatic responsibilities described in M-3, Part I, Chapter 12; Federal Regulations (9 Code of Federal Regulations (CFR) Ch. 1, Subch. A, "Animal Welfare"); and the Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals. Compliance with the PHS Policy is required of all VA medical centers that receive PHS research funds or have a letter of assurance of compliance with PHS Policy on file with OPRR. This directive calls special attention to:
  - (1) Review of research proposals using animals,
  - (2) Oversight of the animal care and use program, and
  - (3) Record keeping for animal use.
- Efforts should be made to avoid duplication of oversight by VA and affiliated organizations without nullifying the responsibilities and obligations contained in M-3, Part I, Chapter 12, the Federal Regulations, and the PHS

Policy.

#### **4. ACTION**

- a. In situations where animal subjects are moved between the VA medical center and its affiliated institutions for research or care and housing, the VA medical center remains accountable for compliance of the research and the care and housing of all animals that are housed at the VA medical center, or held there temporarily for research.
- b. The semi-annual program review of the Institutional Animal Care and Use Committee (IACUC) of an institution that houses, holds temporarily, or conducts research on VA-owned animals may be accepted by the VA medical center provided that the report is submitted to and accepted by the SAS of the VA medical center for the responsible Institutional Official (medical center Director) of the VA medical center. Such reports must be held by the VA medical center and acted upon in accordance with the IACUC findings.
- c. When desirable or feasible, a VA medical center and its affiliated institution may have a joint SAS (or IACUC), provided that the appointment of the committee members is concurred in by the VA medical center responsible Institutional Official, has representation from the VA medical center, and is accountable to the VA medical center Institutional Official. In such cases it is recommended that joint committees have responsibility to the VA medical center and the affiliated institution.
- d. Responsibility for animal subject studies initiated by VA investigators, regardless of funding source, cannot be delegated. It remains the responsibility of the VA medical center to ensure that these studies comply with regulations and policies governing the use of animal subjects in experimentation, irrespective of administrative arrangements with affiliated institutions.
- e. A VA medical center that houses animals belonging to an affiliated institution may accept the animal subject protocol review of the affiliated institution provided that the protocol is submitted to, and accepted by the R&D Committee and the SAS of the VA medical center. Such protocols must be maintained on file, subject to review as described in the Federal Regulations, VA Policy, and PHS Policy when applicable. NOTE: All animal subject protocols submitted to VA Central Office for VA funding must use the VA Animal Component of Research Protocol (ACORP), see M-3, Part I, Chapter 12, Appendix 12C.
- f. When preparing the USDA Annual Report of Research Facility, it is acceptable to report animals owned by the VA medical center, but housed in an affiliated institution, on the VA medical center report form or the report of the affiliated institution. This practice must be consistent across species. It is recommended that when VA medical center animals are reported by affiliated institutions, a copy of the report of the affiliated institution be retained by the VA medical center. Records of ownership and research use of such animals must be retrievable at the VA medical center.

#### **5. REFERENCES**

- a. Manual M-3, Part I, Chapter 12.
- b. Title 7 CFR 2.17, 2.51, and 371.2 (g).
- c. Title 9 CFR Chapter 1 (1-1-92), subchapter A, Animal Welfare.
- d. Title 7 United States Code Sections 2131 through 2157.
- e. OPRR/PHS Policy on Humane Care and Use of Laboratory Animals.

Revised September 1986.

6. RESCISSION: None. This VHA Directive will expire (Date).

7. FOLLOW-UP RESPONSIBILITY: Associate Chief Medical Director for Research and Development (12/4).

S/ by Dennis Smith for  
John T. Farrar, M.D.  
Acting Under Secretary for Health

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**Last updated February 22, 2001**

# National Aeronautics and Space Administration

- [14 CFR 1232 - Care and Use of Animals in the Conduct of NASA Activities](#)
  - [NASA Policy Directive 8910.1 - Care and Use of Animals](#)
  - [NASA Principles for the Ethical Care and Use of Animals](#)
- 

## 14 CFR 1232

### CODE OF FEDERAL REGULATIONS

Effective Date August 22, 1989

Responsible Office: UL

Subject: **CARE AND USE OF ANIMALS IN THE CONDUCT OF NASA ACTIVITIES**

#### SECTION

- 1232.100 [Scope](#).
- 1232.101 [Applicability](#).
- 1232.102 [Policy](#).
- 1232.103 [Definitions](#).
- 1232.104 [Implementation procedures by non-NASA institutions](#).
- 1232.105 [Implementation procedures by NASA field installations](#).
- 1232.106 [Management authority and responsibility](#).
- 1232.107 [Sanctions](#).

AUTHORITY: 42 U.S.C. Sec. 2451; Pub. L. 89-544, as amended; 7 U.S.C. Sec. 2131; 39 U.S.C. Sec. 3001; 9 CFR Subchapter A Parts 1, 2, 3, and 4; and Pub. L. 99-158, Sec. 495.

#### **S 1232.100 Scope.**

This rule establishes the policy, implementation procedures, and management authority and responsibility for the care and use of vertebrate animals (hereinafter referred to as "animal subjects") in the conduct of NASA activities.

#### **S 1232.101 Applicability.**

This rule applies to NASA Headquarters and NASA field installations and will be followed in all activities using animal subjects that are supported by NASA, conducted in NASA facilities, aircraft, or spacecraft, or which involve NASA to any degree. All activities using animal subjects conducted under a contract, grant, cooperative agreement, memorandum of understanding, or joint endeavor agreement entered into by NASA and another Government agency, private entity, non-Federal public entity, or foreign entity are included within the scope of this rule.

#### **S 1232.102 Policy.**

(a) It is NASA policy to require its laboratories and the institutions performing NASA-supported activities using animal subjects to comply with the Animal Welfare Act of 1966 (Pub. L. 89-544), as amended (Pub. L. 91-579, Pub. L. 94-279, and Pub. L. 99-198), 7 U.S.C. Sections 2131 et seq., and 39 U.S.C. Section 3001, and with the regulations promulgated thereunder by the Secretary of Agriculture (9 CFR Subchapter A Parts 1, 2, 3, and 4) pertaining to the care, handling, and treatment of animal subjects held or used for research, testing, teaching, or other activities supported by the Federal government. Investigators shall follow the guidelines described in the National Institutes of Health (NIH) Publication No. 85-23 (Rev. 1985), "*Guide for the Care and Use of Laboratory Animals*" (*the Guide*) or subsequent revisions. Attention is called to the U.S. Government "Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training" on pp. 81-83 of the Guide. In order to implement these guidelines and principles, investigators will comply with the revised Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (hereinafter referred to as PHS Policy) effective November 1, 1986.

(b) This rule authorizes NASA to have the same authority for NASA-supported programs as that delegated to PHS by the PHS Policy, including the functions and responsibilities of the Animal Care and Use Committees (ACUC's).

(c) All research supported by NASA that involves activities using animal subjects shall be conducted under protocols that conform to this rule and that are reviewed and approved as prescribed in this rule.

### **S 1232.103 Definitions.**

The following definitions of terms comply with the PHS Policy and apply to the conduct of all NASA activities related to the care and use of animal subjects.

(a) "Activity" includes research, testing of hardware for animal use, flight experimentation, and any other tasks involving the use of animal subjects.

(b) "Animal" is any live vertebrate animal.

(c) "Animal Care and Use Committee" (ACUC) is the committee established at each institution and NASA field installation involved in research with animal subjects. It is responsible for evaluating the care and use of animal subjects at the facility and for ensuring that the care and use of animal subjects at the facility is in compliance with this rule and PHS Policy.

(d) "Authorized NASA Official" is the Director, Life Sciences Division, NASA Headquarters, or designee, who is the NASA Administrator's representative and is responsible for all NASA activities involving animal subjects. This individual is responsible for implementation of the provisions of this rule and for ensuring that agency programs involving animal subjects comply fully with all applicable laws, regulations, and guidelines.

(e) "Field Installation Director" is the Director of a NASA Field Installation, or designee, who is the institutional official responsible for the care and use of animal subjects in research conducted at that field installation and for ensuring compliance with this rule at that field installation.

(f) "Investigator" is any person who uses or proposes to use live animal subjects in NASA-supported activities, e.g., receives funds, salaries, or support under a grant, award, agreement, contract, or direct employment by NASA, or the use of any NASA facilities, aircraft, or spacecraft for the purpose of carrying out research, tests, or experiments using animal subjects.

(g) "PHS Assurance" is a document prepared by an awardee institution assuring its compliance with PHS Policy.

(h) "Research or Flight Program Manager" is the NASA Headquarters manager of each program in which NASA has a manifest interest.

(i) "Supported" pertains to activities either funded in part or in whole by NASA or an approved activity that is not funded by NASA but that utilizes NASA facilities, including spacecraft and aircraft.

(j) "Veterinarian" is the NASA attending veterinarian, a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education or has a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates, has received training and/or experience in the care and management of the species being attended, and who has direct or delegated authority and responsibility for activities involving animal subjects at the NASA field installation.

#### **S 1232.104 Implementation procedures by non-NASA institutions.**

(a) Proposal Information. No animal subjects may be utilized unless a proposal justifying and describing their use is submitted to NASA for approval. The required proposal information is outlined in the PHS Policy (IV.D.1.a.-e.).

(b) Proposal Approval by the Institutional ACUC. Before a proposal for research involving the use of animal subjects will be considered for NASA support, the NASA Headquarters Research or Flight Program Manager must receive a statement that the research has been reviewed in accordance with the PHS Policy (IV.C.) and approved by the appropriate ACUC at the participating institution.

(c) Proposal Approval for Flight Experiments. In addition to the institution's ACUC review, activities involving animal subjects to be flown on NASA spacecraft will be subject to review and approval by the Ames Research Center (ARC) ACUC. The ARC ACUC will submit each evaluation report to the ARC Director who will transmit the report with his/her recommendation to the Authorized NASA Official, NASA Headquarters. Animal activities to be flown onboard NASA manned spacecraft may also be subject to review by the Human Research Policy and Procedures Committee (HRPPC) at the Johnson Space Center (JSC). Animal activities utilizing the facilities of any NASA field installation are also subject to approval of that field installation's ACUC [S1232.105 (d)].

(d) Institutions with PHS Assurance on File. The institution, by an approved or provisionally acceptable Assurance on file at the NIH Office for Protection from Research Risks (OPRR), Department of Health and Human Services (HHS), assures NASA that it will comply with the PHS Policy. The Assurance file number must be included in the research proposal submitted to NASA.

(e) Institutions with No PHS Assurance on File. Proposals from institutions without an approved Assurance on file with the NIH OPRR will first be peer-reviewed for scientific merit. If the proposed research is deemed worthy of support, NASA will arrange for a special Assurance to be negotiated by the Director, Life Sciences Division, NASA Headquarters. The arrangements for a special Assurance review by NIH should be undertaken in consultation with the NASA representative to the Interagency Research Animal Committee (IRAC) and will be handled on a case-by-case basis.

(f) Foreign institutions must comply with the PHS Policy (see Section II of PHS Policy) and this rule before being supported by NASA for any activities involving animal subjects.

#### **S 1232.105 Implementation procedures by NASA field installations.**

(a) Proposal Information. The information required for proposals involving the use of animal subjects is identical to that described in S1232.104 (a).

(b) Proposal Approval by the NASA ACUC. Before a proposal for research involving the use of animal subjects will be considered for NASA support, the NASA Headquarters Research or Flight Program Manager must receive a statement that the research has been reviewed in accordance with the PHS Policy (IV.C.) and approved by the ACUC at the appropriate field installation.

(c) Proposal Approval for Flight Experiments. In addition to the Field Installation ACUC review, activities involving animal subjects to be flown on NASA spacecraft will be subject to review and approval by the ARC ACUC. The ARC ACUC will submit each evaluation report to the ARC Director who will transmit the report with his/her recommendation to the Authorized NASA Official, NASA Headquarters. Animal activities to be flown onboard NASA manned spacecraft may also be subject to review by the HRPPC at JSC.

(d) Approval for Use of Field Installation Facilities. The NASA Field Installation ACUC will review and approve or disapprove those parts of proposals that call for the use of their facilities to conduct any activity involving animal subjects (e.g., Kennedy Space Center or ARC Dryden facilities used to support experiments using animal subjects). The ACUC will submit each evaluation report to the Field Installation Director who will transmit the report with his/her recommendation to the Authorized NASA Official, NASA Headquarters.

(e) NASA Animal Care and Use Committees.

(1) The Director of each NASA Field Installation that is involved in animal research activities will establish an ACUC to ensure compliance with the policies and provisions of this rule. The membership of the ACUC shall be in accordance with PHS Policy.

(2) The NASA Field Installation ACUC's will review and approve or disapprove all proposals using animal subjects. In accordance with the PHS Policy (IV.C.), the ACUC will submit each report to the Field Installation Director who will, upon request, transmit the report with his/her recommendation to the Authorized NASA Official, NASA Headquarters.

(3) NASA ACUC's have the authority to approve, disapprove, or require changes to be made in those components of proposals involving the care and use of animal subjects that are submitted by NASA investigators. All decisions shall be based on the response of a majority of a quorum of the members. A minority opinion including abstentions should be recorded; this record should include a justification for the opinion.

(4) The ACUC shall conduct continuing review of proposals at appropriate intervals as determined by the ACUC, but not less than once every 3 years.

(5) Proposals that have been approved by the ACUC may be subject to further appropriate review by the Authorized NASA Official, NASA Headquarters. However, the official may not approve those sections of a proposal related to the care and use of animal subjects if they have not been approved by the ACUC.

(6) Once experimental procedures are approved, no substantial changes can be made unless a formal request with appropriate justification for such a request is submitted to and approved by the appropriate ACUC. If the experiment involves exposure of the flight crew to the animal subjects, the HRPPC at JSC must review and approve the proposed modifications. Copies of ACUC approval of the proposed modifications shall be submitted to the Field Installation Director who will, upon request, transmit the report to the Authorized NASA Official, NASA Headquarters.

(7) Other functions of the field installation ACUC include:

(i) Reviewing at least once every 6 months the field installation's program for humane care and use of animals, using the Guide as a basis for evaluation;

(ii) Inspecting at least once every 6 months all of the field installation's animal facilities (including satellite facilities), using the Guide as a basis for evaluation;

(iii) Preparing reports of the ACUC evaluations conducted as required by S1232.105 (e)(7)(i) and (ii), and submitting the reports to the Field Installation Director. (Note: the reports shall be updated at least once every 6 months upon completion of the required semiannual evaluations and shall be maintained by the field installation and made available to the Authorized NASA Official upon request. The reports must contain a description of the nature and extent of the field installation's adherence to the Guide and this rule and must identify specifically any departures from the provisions of the Guide and this rule, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, consistent with PHS Policy, and, in the judgment of the

ACUC and the Field Installation Director, 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.)

(iv) Reviewing concerns involving the care and use of animals at the field installation;

(v) Making recommendations to the Field Installation Director regarding any aspect of the field installation's animal program, facilities, or personnel training.

(f) NASA Assurances. Each NASA field installation involved in activities using animal subjects must assure that its programs and facilities have been evaluated and accredited by the American Association for the Accreditation of Laboratory Animal Care (AAALAC). Written assurance of compliance with the provisions of the PHS Policy and this rule is also required from NASA field installations involved in animal activities before approval of any such activity. This Assurance should follow the sample PHS Assurance format shown on pages 19-26 of the PHS Policy and must be submitted by the Field Installation Director to the Authorized NASA Official. The Assurance is subject to renewal every 5 years.

(g) Recordkeeping Requirements.

(1) Each NASA field installation involved in activities using animal subjects shall maintain:

(i) An Assurance of compliance with PHS Policy and this rule [S1232.105 (f)];

(ii) Minutes of ACUC meetings, including records of attendance, activities of the committee, and committee deliberations;

(iii) Records of applications, proposals, and proposed significant changes in the care and use of animals and whether ACUC approval was given or withheld;

(iv) Records of semiannual ACUC reports and recommendations (including minority views) as forwarded to the Field Installation Director,

(v) Records of AAALAC accreditation; and

(vi) The Field Installation's Animal Users Guide and Animal Care Facility Management Manual. The Field Installation Animal Users Guide and Animal Care Facility Management Manual should be revised at appropriate intervals.

(2) All records shall be maintained for at least 3 years; records that relate directly to applications, proposals, and proposed significant changes in ongoing activities reviewed and approved by the ACUC shall be maintained for the duration of the activity and for an additional 3 years after completion of the activity. All records shall be furnished upon request to the Authorized NASA Official.

(h) Reporting Requirements. For each NASA field installation involved in activities using animal subjects:

(1) Statements of ACUC approval of research proposals, ACUC evaluation reports of flight experiment proposals and of experiment proposals utilizing field installation facilities, and the field installation's

Assurance of compliance shall be submitted in the manner prescribed in S1232.104 (c) and S1232.105 (b) (c) (d) and (f).

(2) At least once every 12 months, the ACUC, through the Field Installation Director, shall report in writing to the Authorized NASA Official:

- (i) Any change in the field installation's program or facilities that would affect the AAALAC accreditation status;
- (ii) Any change in the description of the field installation's program for animal care and use;
- (iii) Any changes in the ACUC membership;
- (iv) Notice of the dates that the ACUC conducted its semiannual evaluations of the field installation's program and facilities and submitted the evaluations to the Field Installation Director;
- (v) A statement that the field installation has no changes to report as specified in S1232.105 (h) (2) (i) (ii) or (iii) of this rule, if there are no changes.

(3) The ACUC, through the Field Installation Director, shall promptly provide the Authorized NASA Official with a full explanation of the circumstances and actions taken with respect to:

- (i) Any serious or continuing noncompliance with this rule and PHS Policy;
- (ii) Any serious deviation from the provisions of the Guide; or
- (iii) Any suspension of an activity by the ACUC.

(4) Reports filed under S1232.105 (h) of this rule shall include any minority views filed by members of the ACUC.

(5) A copy of the U.S. Department of Agriculture (USDA) Annual Report will be furnished to the Authorized NASA Official.

### **S 1232.106 Management authority and responsibility.**

(a) Authorized NASA Official. The Authorized NASA Official is the NASA Administrator's representative and is responsible for all NASA activities involving animal subjects. This individual is responsible for implementation of the provisions of this rule and for ensuring that agency programs involving animal subjects comply fully with all applicable laws, regulations, and guidelines.

(b) Field Installation Director. The Field Installation Director is responsible for and has the authority to:

- (1) sign the field installation's Assurance, making a commitment on behalf of the field installation that the requirements of the PHS Policy and this rule will be met in all field installation activities involving animal subjects;
- (2) create and oversee the functioning of the field installation ACUC;

- (3) decide and administer sanctions in cases of noncompliance with this rule;
- (4) fulfill the reporting requirements assigned to this individual in S1232.105 (h); and
- (5) sign the annual USDA report.

(c) NASA Field Installation(s) ACUC Responsibility. Each NASA Field Installation ACUC is responsible to its Field Installation Director for the activities described in S 1232.104 (c) and S 1232.105 (b) (c) (d) (e) and (h).

(d) Research or Flight Program Manager Responsibility. The Research or Flight Program Manager is responsible for ascertaining the presence of the required PHS Assurance file number for proposals involving animal subjects received from non- NASA institutions, and a statement of ACUC review and approval of all NASA and non-NASA proposals involving animal subjects. No awards for activities involving animal subjects can be made without this documentation [see S1232.104 (b) and (d) and S 1232.105 (b)].

(e) NASA Veterinarian(s) Responsibility. NASA veterinarian(s) have direct or delegated authority and responsibility for activities involving animal subjects at their field installation. Such authority and responsibilities shall include recommending approval or disapproval of procedures involving animal subjects as a member of the ACUC, continual monitoring of these activities, surveillance of the health and condition of animal subjects, and reporting any observed deviations from approved procedures involving animal subjects to the Field Installation Director and the ACUC. In the case of deviation from ACUC- approved practices or procedures, the veterinarian shall have the authority to immediately halt such procedures until they are reviewed and resolved by the ACUC. In cases of a conflict concerning animal usage by an investigator that cannot be resolved between him/her and the veterinarian, the matter may be brought to the attention of the Field Installation ACUC for review and recommendation for action as set forth in this rule. Whereas the performance of the veterinarian's duties can be delegated to other qualified individuals, the ultimate responsibility rests with the veterinarian. This responsibility extends not only to the Animal Care Facility (ACF), but also to other locations where animal subjects are used. Other specific areas of responsibility and authority vested in the veterinarian are:

- (1) Entry of personnel into the ACF. The veterinarian has the responsibility to develop access procedures to the ACF and submit them to the ACUC for approval.
- (2) Personnel Training. The veterinarian will participate in the training of personnel in the handling of animal subjects and in specimen sampling procedures.
- (3) Animal Training. The veterinarian will monitor all schedules and procedures involving the training and acclimation of animal subjects.
- (4) Surgery and Surgical Procedures. The veterinarian will monitor all surgical procedures and verify that the principles of the Guide with regard to aseptic surgery are employed. Post- surgical recovery procedures are included. If necessary, training will be provided by the veterinarian to bring procedures conducted by investigators to the level of these standards.
- (5) Veterinary Medical and Engineering Procedures. The veterinarian will monitor all veterinary medical and engineering procedures performed on animal subjects and verify their appropriateness. The veterinarian will actively participate in identifying and/or establishing the design requirements and adequacy of animal facilities for ground and spaceflight-related activities.

(f) NASA Representative to the Interagency Research Animal Committee (IRAC). The NASA representative to the IRAC will obtain information of all cases in which an institution's Assurance has been revoked by the PHS. The NASA IRAC representative will notify NASA ACUC's, Field Installation Directors, the Authorized NASA Official, and all Headquarters Research and Flight Program Managers so that they can determine which NASA awards involving the use of animal subjects are affected and can take appropriate sanctions.

## S 1232.107 Sanctions.

(a) Non-NASA Institutions. Principal investigators not employed by NASA whose activities are supported by NASA but whose activities using animal subjects are restricted to non-NASA facilities shall be subject to the control of their institution's ACUC and responsible institutional official. Notification of noncompliance with this rule shall be made either as described in S 1232.106 (f) or by the non-NASA institution to the Director of the NASA Field Installation through which the activity has been supported and to the Authorized NASA Official. Any continued noncompliance may be cause for termination of funding or support.

(b) NASA Field Installations.

(1) Inappropriate procedures on animal subjects by NASA principal investigators shall be halted by the NASA Field Installation Veterinarian or line management and brought to the attention of the ACUC if the issue cannot be immediately resolved. The ACUC will review the activity and report any noncompliance with this rule to the Field Installation Director. Principal investigators not employed by NASA, whose activities using animal subjects are performed in NASA facilities, aircraft, or spacecraft, are subject to similar action. Such noncompliance will be cause for sanctions. The principal investigator can contest, in writing, these decisions to the ACUC.

(2) The ACUC as the agent of the Field Installation Director 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, PHS Policy requirements, or this rule.

(3) Any suspension or termination of approval will include a statement of the reasons for the action and will be promptly reported to the principal investigator and the appropriate Field Installation Director. In the case of investigators from non-NASA institutions, notification should be sent to the investigator, the appropriate institution, and the Director of the Field Installation through which the activity has been supported. If the ACUC suspends an activity involving animal subjects, the Field Installation Director in consultation with the ACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to the Authorized NASA Official, NASA Headquarters. If an ACUC recommends disapproval, suspension, termination, or conditional approval of an activity, the principal investigator will be given the opportunity to ask for reconsideration of the decision in person and/or in writing to the appropriate NASA ACUC.

(4) If, after notification of the Field Installation Director and an opportunity for correction, such deficiencies or deviations remain uncorrected, the ACUC will notify (in writing) the Authorized NASA Official, NASA Headquarters, who is then responsible for all corrective action to be taken.

/s/Richard H. Truly  
Administrator  
National Aeronautics and Space Administration

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# NASA Policy Directive

Directive: NPD 8910.1

Effective Date: March 23, 1998

Expiration Date: March 23, 2003

Responsible Office: UL / Life Sciences Division

Subject: **Care and Use of Animals**

## 1. POLICY

- a. NASA will conduct activities involving vertebrate animals, recognizing its responsibility for the stewardship of the animals and to the scientific community and society and adhering to the ethical principles of respect for life, societal benefit, and non-maleficence.
- b. All activities to which this NPD applies will comply with the "Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals"(PHS Policy) and the guidelines in the National Research Council's "*Guide for the Care and Use of Laboratory Animals*" (*the Guide*).
- c. All NASA Centers (including Component Facilities) conducting activities, regardless of funding source, involving animals will, at all times, be covered by a current Animal Welfare Assurance (Assurance) approved by the Office for Protection from Research Risks (OPRR), National Institutes of Health.
- d. All NASA Centers (including Component Facilities) conducting activities involving animals will actively seek to receive and maintain accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

## 2. APPLICABILITY

This NPD applies to NASA Headquarters and NASA Centers, including Component Facilities, and to all activities involving animals funded by or sponsored by NASA, or conducted in or on NASA facilities, aircraft, or spacecraft. Such activities include those conducted under a cooperative agreement or grant, reimbursable agreement, or other arrangement or agreement, entered into by NASA and another Government agency, private entity, non-Federal public entity, or foreign entity.

## 3. AUTHORITY

- a. 42 U.S.C. Sec. 2473(c)(1), Sec. 203(c)(1) of the National Aeronautics and Space Act of 1958, as amended.
- b. 7 U.S.C. Sec. 2131 et seq., the Animal Welfare Act of 1966, as amended.

## 4. REFERENCES

- a. 14 CFR Part 1232, *Care and Use of Animals in the conduct of NASA Activities*.
- b. U.S. Department of Health and Human Services, *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (1986).
- c. National Research Council, *Guide for the Care and Use of Laboratory Animals* (1996).
- d. United States Interagency Research Animal Committee, *U.S. Government Principles for the Utilization and Care of*

*Vertebrate Animals Used in Testing, Research, and Training* (1985).

e. Council for International Organizations of Medical Sciences, *International Guiding Principles for Biomedical Research Involving Animals* (1985).

f. 9 CFR Subchapter A, Parts 1,2,3, and 4, U.S. Department of Agriculture (USDA), Animal Welfare.

## **5. RESPONSIBILITY**

a. The Associate Administrator for the Office of Life and Microgravity Sciences and Applications (AA for Code U) has overall responsibility for this NPD, including the designation of the authorized NASA official.

b. The Director of the Life Sciences Division (Code UL) will be the authorized NASA official responsible for the following:

(1) Implementing the provisions of this NPD and ensuring that all Agency programs and activities involving animals comply fully with all applicable laws, regulations, and guidelines.

(2) Representing NASA on, or designating a representative for, the Federal Interagency Research Animal Committee (IRAC).

(3) Establishing and maintaining mechanisms for obtaining timely information from OPRR of all cases in which the Assurance of an institution involved in NASA research has been withdrawn by the PHS; and notifying NASA's Institutional Animal Care and Use Committees (IACUC), Center Directors, and Research and Flight Program Managers of such revocations so that they can determine if NASA awards involving the use of animals are affected and take appropriate actions. The authorized NASA official may designate a representative for these functions.

(4) Reviewing all sanctions imposed by Center Directors or IACUC's to determine if further sanctions are warranted or, at his or her discretion, initiating investigations of alleged noncompliance with this NPD and imposing sanctions when warranted.

(5) Appointing the NASA Chief Veterinarian, who will be a NASA civil service employee.

c. Center Directors are responsible for the following:

(1) Signing the Center's Assurance, making a commitment on behalf of the Center that the requirements of this NPD will be met. Center Directors may delegate authority for the day-to-day management of their Centers' Animal Care and Use Program but they retain the ultimate responsibility for ensuring compliance with this NPD, the Animal Welfare Act, PHS policy, and the Guide at their Centers.

(2) Establishing and supervising the functioning of their Centers' IACUC. This responsibility may be accomplished through the use of another Center's IACUC via a formal inter-Center agreement.

(3) Signing and submitting to OPRR the Animal Welfare Assurance, committing the Center to the requirements of the PHS policy and this NPD in all Center activities involving animal subjects and providing copies of the approved Assurance, OPRR letter of approval, and any OPRR correspondence to the authorized NASA official.

(4) Signing the application for AAALAC International Accreditation and the annual AAALAC International reports, and providing copies of the AAALAC International Accreditation letter, the annual reports, and any correspondence from AAALAC International to the authorized NASA official.

(5) Signing the annual report to USDA and providing copies of the report and any comments from USDA to the authorized NASA official.

(6) Deciding and administering sanctions in cases of noncompliance with this NPD in accordance with the Animal Welfare Act, PHS policy, and applicable NASA regulations, and notifying appropriate funding officials and the authorized NASA official.

(7) Providing the authorized NASA official with copies of all IACUC minutes and reports.

d. The NASA IACUC's are responsible for approving any animal use conducted at their Centers.

e. The NASA Ames Research Center (ARC) IACUC, in addition to approving any animal use conducted at ARC, is responsible for reviewing and approving all NASA-supported flight activities in the United States involving animals, regardless of launch site or site of performance (includes both aircraft and spacecraft vehicles). This responsibility may be delegated to another Agency IACUC with the approval of the authorized NASA official. The ARC IACUC will also review all NASA-supported flight activities involving animals which are conducted in other countries; however, the primary responsibility for those activities rests with the host country.

f. The NASA Chief Veterinarian is responsible for the following:

(1) Coordinating veterinary and animal care activities on an Agencywide basis. In accomplishing this responsibility, the NASA Chief Veterinarian is specifically authorized to suspend any animal activity believed to be noncompliant with applicable laws, regulations, this policy, and approved protocols. Following suspension of any activity, the Chief Veterinarian will initiate action, including IACUC re-review, to resolve the situation.

(2) Guiding, as Chairperson, the activities of the Intercenter Animal Care and Use Coordination Team (IACUCT), composed of Center veterinarians (serving, on a rotating basis, as Executive Secretary); Chairs of each Center's IACUC; other representatives of each Center as appointed by Center Directors; and a public affairs specialist, a legal advisor, and others, as appointed by the authorized NASA official.

(3) Advising the authorized NASA official on any aspect of the Agency's Animal Care and Use Program.

(4) Representing NASA in the external laboratory animal science community and associations such as the American Association for Laboratory Animal Science and the American College of Laboratory Animal Medicine.

(5) Maintaining coordination with the International Council for Laboratory Animal Science (ICLAS);

(6) Participating in development of requirements for all animal facilities and equipment for flight as related to animal care and use.

(7) Developing and implementing a program to foster and encourage the use of alternate methods of research that reduce the numbers of animals used, refine the procedures used to minimize or eliminate animal pain or distress, or encourage the use of procedures that do not require the use of animals. As part of this effort, the NASA Chief Veterinarian will establish and maintain liaison with organizations working in this field and will develop and maintain mechanisms for dissemination of information regarding new methods and protocols to potentially interested parties.

(8) Developing and implementing for non-NASA investigators an education program intended to inform them regarding the requirements and constraints for flight animal research activities inflight.

(9) Informing foreign entities and individuals about the technical requirements in accordance with U.S. laws, regulations, guidelines, standards, and this NPD. This will include information regarding the requirements and constraints for flight animal research activities, as well as sources for electronic and hard copy access to animal care and use information.

## 6. DELEGATION OF AUTHORITY

None.

## 7. MEASUREMENTS

Adherence to this NPD will be measured through strict implementation of requirements outlined herein and detailed in NASA NPG 8910. In general terms, for all NASA-sponsored research involving animals, the requirements will include accreditation and certifications, review and approval by the appropriate IACUC's, and specified monitoring.

## 8. CANCELLATION

None.

/s/ Daniel S. Goldin  
Administrator  
National Aeronautics and Space Administration

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# NASA Principles for the Ethical Care and Use of Animals

A strong allegiance to the principles of bioethics is vital to any discussion of responsible research practices. As reflected in the considerations of the National Commission for the Protection of Human Subjects, "scientific research has produced substantial social benefits ... [and] some troubling ethical questions" (The Belmont Report, 1979). The Belmont Report identified the key fundamental principles underlying the ethical evaluation of research involving human subjects. Similarly, the principles governing the ethical evaluation of the use of animals in research must be made equally explicit.

It is generally agreed that vertebrate animals warrant moral concern. The following principles are offered to guide careful and considered discussion of the ethical challenges that arise in the course of animal research, a process that must balance risks, burdens, and benefits. NASA will abide by these principles as well as all applicable laws and policies that govern the ethical use of animals (see list at end). It is recognized that awareness of these principles will not prevent conflicts. Rather, these principles are meant to provide a framework within which challenges can be

rationally addressed.

## **Basic Principles**

The use of animals in research involves responsibility, not only for the stewardship of the animals but to the scientific community and society as well. Stewardship is a universal responsibility that goes beyond the immediate research needs to include acquisition, care and disposition of the animals, while responsibility to the scientific community and society requires an appropriate understanding of and sensitivity to scientific needs and community attitudes toward the use of animals.

Among the basic principles generally accepted in our culture, three are particularly relevant to the ethics of research using animals: respect for life, societal benefit, and non-maleficence.

### **1. Respect for Life**

Living creatures deserve respect. This principle requires that animals used in research should be of an appropriate species and health status and that the research should involve the minimum number of animals required to obtain valid scientific results. It also recognizes that the use of different species may raise various ethical concerns. Selection of appropriate species should consider cognitive capacity and other morally relevant factors. Additionally, methods such as mathematical models, computer simulation, and in vitro systems should be considered and used whenever possible.

### **2. Societal Benefit**

The advancement of biological knowledge and the improvements in the protection of the health and well being of both humans and other animals provide strong justification for biomedical and behavioral research. This principle entails that in cases where animals are used, the assessment of the overall ethical value of such use should include consideration of the full range of potential societal goods, the populations affected, and the burdens that are expected to be borne by the subjects of the research.

### **3. Non-maleficence**

Vertebrate animals are sentient. This principle entails that the minimization of distress, pain, and suffering is a moral imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in humans may cause pain or distress in other sentient animals.

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**Last updated February 16, 2001**

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

**Revised September, 1986**

Reprinted March, 1996

**NATIONAL INSTITUTES OF HEALTH  
OFFICE OF THE DIRECTOR**

The full-text of this policy is available at <http://grants.nih.gov/grants/olaw/references/phspol.htm>

## **PREFACE**

This 1996 reprint of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals is substantively identical to the original Policy promulgated in 1986 to implement the Health Research Extension Act of 1985 (Public Law 99-158). Citations and addresses are updated and some language is clarified to eliminate common areas of confusion. The U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training appear in a more prominent location to emphasize their importance.

The Office of Laboratory Animal Welfare (formerly Office for Protection from Research Risks, Division of Animal Welfare) at the National Institutes of Health, which has responsibility for the general administration and coordination of the Policy on behalf of the PHS, provides specific guidance, instruction, and materials to institutions that must comply with the Policy. For copies of supplemental materials, please contact OLAW at the National Institutes of Health, RKL1, Suite 1050, MSC 7982, 6705 Rockledge Drive, Bethesda, Maryland 20892-7982. NOTE, for Express or Hand Delivered Mail, Use Zip Code 20817.

## **ABSTRACT OF PHS POLICY**

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals sets forth the requirements that are applicable to all research, research training, biological testing, and related activities involving animals that are supported or conducted by agencies of the PHS. The Office of Laboratory Animal Welfare at the National Institutes of Health is responsible for the general administration and coordination of the Policy.

The Policy is mandated by the Health Research Extension Act of 1985 (Public law 99-158), and implements the U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training. Included in the Policy are institutional responsibilities for Animal Welfare Assurances, Institutional Animal Care and Use Committees (IACUCs), review of projects, programmatic evaluations, facility inspections, record keeping and reporting. Specific criteria for IACUC review of projects, and frequency and methods of review are described. The information required by the PHS in applications or proposals when animals are to be involved, and PHS responsibilities for implementing the Policy, are also included.

5/09/96

**Editor's Note: Please note that in the policy that follows "OPRR Office of Protection from Research**

Risks" should be replaced by "OLAW Office of Laboratory Animal Welfare."

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### 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.

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.

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

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## **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 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, HHS, NIH Pub. No. 86-23, 1985 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 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 PHS currently includes the Agency for Health Care Policy Research, 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 for Protection from Research Risks (OPRR), Office of the Director, National Institutes of Health.<sup>1</sup> The Assurance shall be typed on the institution's letterhead and signed by the Institutional Official. OPRR 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 OPRR 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 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-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.<sup>2</sup>

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 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; <sup>3</sup>
- 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 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 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 another accrediting body recognized by PHS.<sup>4</sup> 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.

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 semi-annual report of the IACUC evaluation shall be submitted to OPRR 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.<sup>5</sup>
- 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 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.

## **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;<sup>6</sup>
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;<sup>7</sup>
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. (NOTE: the reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the institution and made available to OPRR upon request. 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. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, 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. If some or all of the institution's facilities are accredited by AAALAC or another accrediting body recognized by PHS, the report should identify those facilities as such.);
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.<sup>8</sup> 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 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.<sup>9</sup>

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.

3. The IACUC may invite consultants to assist in 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 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.<sup>10</sup> 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 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-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;
- 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. 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) covered by this Policy from institutions which have an approved Assurance on file with OPRR 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 a time not to exceed 60 days after the receipt deadline date. 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 OPRR, the signature of the official signing for the applicant organization shall constitute a declaration that the institution will submit an Assurance when requested by OPRR. Upon such request, the institution shall prepare the Assurance as instructed by OPRR 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 OPRR.

## **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, 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 OPRR 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 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. 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; 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 submit a letter, through the Institutional Official, to OPRR stating that there are no changes and informing OPRR of the dates of the required IACUC evaluations and submissions to the Institutional Official.

3. The IACUC, through the Institutional Official, shall promptly provide OPRR 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*; 11 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 PHS**

### **A. Responsibilities of the Office for Protection from Research Risks (OPRR)**

OPRR 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 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 OPRR, 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 OPRR, the awarding unit will ask OPRR 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 OPRR, 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 advisors, which may include a site visit, in order 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 OPRR. No waiver will be granted unless sufficient justification is provided and the waiver is approved in writing by OPRR.

## **FOOTNOTES**

### **Footnote 1:**

Assurances should be sent to the Division of Animal Welfare, Office for Protection from Research Risks, National Institutes of Health, 6100 Executive Boulevard, MSC 7507, Suite 3B01, Rockville, Maryland 20892-7507. The address for express or hand-delivered mail is Division of Animal Welfare, Office for Protection from Research Risks, National Institutes of Health, 6100 Executive Boulevard, Suite 3B01, Rockville, Maryland 20852.

### **Footnote 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 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.

### **Footnote 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.

### **Footnote 4:**

As of the 1996 reprint of this Policy, the only accrediting body recognized by PHS is the American Association for Accreditation of Laboratory Animal Care (AAALAC)

### **Footnote 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. OPRR 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.).

**Footnote 6:**

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 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.

**Footnote 7:**

The Institutional Animal Care and Use Committee (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.

**Footnote 8:**

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 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.

**Footnote 9:**

Journal of the American Veterinary Medical Association (JAVMA), 1993, Vol. 202, No. 2, pp. 229-249, or succeeding revised editions.

**Footnote 10:**

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 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.

**Footnote 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 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.

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