

ARS □ CSREES □ ERS □ NASS

Policies and Procedures

Title: Animal Care and Use Committee

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

This Directive also provides current address information as of July 19, 2002.

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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.

8. 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.

9. 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.

10. 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. c 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. f 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.

11. 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.

12. 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, Dr. Michael P. Kiley, 5601 Sunnyside Avenue, Bldg. 4-2174, Beltsville, Maryland 20705-5138.

Retain:

One certified copy for file.

NOTE: Discard copies after 3 years.

R. D. PLOWMAN

Administrator

Exhibits (NOT AVAILABLE IN ELECTRONIC VERSION)

- 1 Animal Welfare Act, 9 CFR Parts 1, 2C, and 3
- 1A Amendment to 9 CFR Part 3 (Animal Welfare: Guinea Pigs; Hamsters; and Rabbits)
- 2 APHIS Form 7008 (replaces VS Form 18-8 which is obsolete), APHIS - VS Forms 18-1, 18-5, 18-6, 18-23, and Addressees of Sector Supervisors, REAC, APHIS
- 3 ARS Forms 605 and 606
- 4 Interagency Research Animal Committee's US 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