NIH POLICY MANUAL

3040-2 ANIMAL CARE AND USE IN THE INTRAMURAL PROGRAM
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1. **Explanation of Material Transmitted:** This revised chapter establishes responsibility for humane care and use of animals within the intramural program of NIH.

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NIH MANUAL 3040-2 -Table of Contents
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ANIMAL CARE AND USE IN THE INTRAMURAL PROGRAM

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A. PURPOSE: This policy establishes responsibility for humane care and use of animals within the Intramural Research Program (IRP) of the National Institutes of Health (NIH).

B. REFERENCES: See Appendix 2.

C. DEFINITIONS:

1. **Accreditation** - The recognition by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) or other Public Health Service (PHS)-recognized accrediting body that the animal facilities and management practices of a research institution are in accordance with the Guide. (See C.11.)

2. **Adequate Veterinary Care** - The standards set forth in Adequate Veterinary Care by the American College of Laboratory Animal Medicine and the Animal Welfare Regulations (AWRs).

3. **Animal** - Any live vertebrate animal used or intended for use in research, experimentation, testing, training, or related purposes. This definition shall extend to animals that are acquired for the purpose of collecting tissues or other parts. (The acquisition and transportation of certain invertebrates and parts of certain vertebrates are also subject to Federal regulation.)

4. **Animal Exposure Surveillance Program (AESP)** - That portion of the NIH occupational health program, managed by the Occupational Medical Service, Division of Safety, specifically designed for all NIH personnel who work in animal facilities and who have significant contact, as determined by the Principal Investigator, with research animals or their tissues that have not been treated to assure freedom from pathogens, and others who work in areas where research animals are housed or used. Institute/Center (IC) (See C.12.) programs outside the metropolitan Washington DC area, e.g. NCRR's Alamogordo Primate Facility (APF), NIA, NIDA, NIEHS and NIAID-RML, shall implement equivalent programs, as appropriate.

5. **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 animal facility or centrally designated or managed area in which animals are housed for more than 24 hours. [Per PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy).] (See C.21.)

   CENTRAL ANIMAL FACILITY: An animal facility managed by the Veterinary Resources Program (VRP), Office of Research Services (ORS), and utilized by more than one Institute/Center (IC).

SHARED ANIMAL FACILITY: A core animal facility shared by more than one IC and managed by a Lead IC.

STUDY AREA: Any building room, area, enclosure or other containment outside of a core facility or centrally designated or managed area in which animals are housed more than 12 hours. (Per AWRs.)

6. **Animal Research Advisory Committee (ARAC)** - The intramural NIH institutional Animal Research Advisory Committee includes the Chair of each IC Animal Care and Use Committee (ACUC). (See C.13.) The Deputy Director for Intramural Research shall appoint the Chair, Executive Secretary and additional members in concert with the PHS Policy and the AWRs.

7. **ARAC Guidelines** - Guidelines developed and approved by the ARAC.

8. **Animal Study Proposal** - The form completed by a Principal Investigator and submitted to the Chair, IC ACUC for review and approval prior to the ordering of animals or initiation of the study. (See Appendix 1.)

9. **Animal Program Directors Committee** - A committee established to provide advice and guidance on veterinary issues to the Director, Office of Animal Care and Use. The committee includes the Animal Program Director of each IC. (See C.28.)

10. **Animal Welfare Act Regulations (AWRs)** - Regulations promulgated by the United States Department of Agriculture, Animal and Plant Health Inspection Service, pursuant to the authority in the Animal Welfare Act 7 U.S.C. 2131, et seq and contained in 9 CFR, Parts 1, 2, and 3.

11. **Guide** - The NRC Guide for the Care and Use of Laboratory Animals, which serves as the standard by which animal care and use programs are developed and assessed. The Guide is available from the Office of Animal Care and Use (OACU), OD, NIH, Building 31, Room B1C37, 301-496-5424.

12. **Institute/Center (IC)** - For the purposes of this Policy Manual and the NIH IRP Animal Care and Use (ACU) program, each IC is presumed to be directed by a single Institute Director; the IC's intramural research program is directed by an individual program director, e.g. Scientific Director; when research with animals is conducted by staff within that IC there is one IC-ACUC (See C.13.) and one Animal Program Director (APD).(See C.28.) Exceptions are noted within the NIAID, NCI, and NCRR as follows: a) the NIAID has three intramural components, each with an ACUC and an APD - those components include the NIAID Division of Intramural Research and the Rocky Mountain Laboratories (See C.19.) which are directed by one NIAID Scientific Director, and the NIAID Vaccine Research Center, which is directed by a separate Scientific Director; b) the NCI has one Scientific Director, one APD, one NCI-wide ACUC, and two operational ACUCs that carry

out the duties described in paragraph F.11(b); c) the NCRR does not have an intramural component, however, through a Memorandum of Understanding, the NCRR's Alamogordo Primate Facility is recognized as a component of the NIH IRP ACU program, is subject to the provisions of this Policy, and is also a component of the Institutional Assurance. (See C.15.)

13. **IC-Animal Care and Use Committee (IC-ACUC)** - A committee appointed (via delegated authority from the Director, NIH through the Deputy Director for Intramural Research) by the Director or Scientific Director (SD), of an IC that uses animals in its intramural research program. The committee oversees the IC's animal program, facilities and procedures, including the key functions of reviewing and approving requests to use animals in research Animal Study Proposals.

14. **Institution** - The NIH intramural program including facilities in Bethesda, other NIH facilities separate from the main campus, or contracted or subcontracted activities performed in accordance with NIH Manual 3040-3 or other applicable acquisition regulations, in support of the intramural program.

15. **Institutional Assurance** - The Animal Welfare Assurance filed with the NIH Office of Laboratory Animal Welfare (OLAW) certifying that the NIH intramural research program is in compliance with the PHS Policy.

16. **Institutional Official** - The NIH Deputy Director for Intramural Research (DDIR). The Director, NIH, as the Chief Executive Officer of the institution, has delegated to the DDIR the authority and responsibility for compliance of the NIH Intramural Research program with PHS Policy, the Guide, and the AWRs. This includes authority to direct the allocation of resources to correct deficiencies.

17. **Intraagency Agreement** - A formal written agreement that describes understandings between the parties occupying a Shared or Central Animal Facility. The Agreement assigns responsibilities and authorities and establishes a mechanism for funding and other resources needed to support the operation of the facility and/or care of animals housed in the facility. At a minimum, the Agreement shall: a) state the purpose of the agreement; b) delineate the period of the agreement; c) specify the authorities and responsibilities of each party; d) define the reimbursement, financial responsibilities of each party; e) describe the billing procedures to be utilized; and f) contain the concurrence of individuals authorized to sign the Agreement in accordance with the authority outlined in Section 601 of the Economy Act of 1932, as amended (U.S.C. 1535.) In addition, agreements in Shared Animal Facilities shall include: 1) the management plan/standard operating procedures of the facility; and 2) the composition, structure and function of the User Committee. In all agreements, the Lead IC Animal Program Director must be delegated the authority, from the Lead IC Director or Scientific Director, to: a) ensure timely adequate veterinary care of all animals in the animal facility; b) ensure compliance with all applicable regulations, guidelines and policies; and c) maintain AAALAC accreditable standards of the ACU

program and facility. (See NIH Manual 1165.)

18. **Lead Institute** - The user IC, which other user ICs authorize through an intraagency agreement, to manage a Shared Animal Facility(ies).

19. **NIAID-RML** - The NIAID - Rocky Mountain Laboratories (RML) ACU program is managed as a second, separate program from that based on the Bethesda campus and reports to the NIAID DIR SD. The RML Attending Veterinarian (See C.28.) serves as an Animal Program Director and the RML ACUC Chair serves as a member of the ARAC. (See C.6.)

20. **Office of Animal Care and Use (OACU)** - The office with authority to act on behalf of the Institutional Official to ensure that NIH programs and facilities for ACU are in compliance with this policy, the Guide, the PHS Policy and the AWRs. This authority is exercised by the Director, OACU.

21. **PHS Policy** - Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, Revised as of September l986, or subsequent editions.

22. **Principles** - U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training - (See Appendix 3.)

23. **Principal Investigator** - A scientist designated by the Laboratory/Branch Chief or the IC Director or Scientific Director responsible for conducting an animal study in compliance with this policy, the Guide, the PHS Policy, and the AWRs, and who certifies acceptance of this responsibility by signing the Animal Study Proposal.

24. **Refinement** - Refinements in animal research are those which alleviate or minimize the pain, distress or other adverse effects experienced by the animals involved, and/or enhance animal well-being. Refinements may be applied at any stage in the use of the laboratory animal, from its birth to its death. It can include such aspects of a procedure as: the source, transport, husbandry, and environment of the animals involved; the experimental design (e.g., group sizes are reduced), the techniques applied; the care of the animals before, during and after a procedure; the endpoints of the procedures; and the method of killing the animals.

25. **Satellite Facility** - See C.5.

26. **Study Area** - Any building room, area, enclosure or other containment outside of a core facility or centrally designated or managed area in which animals are housed more than 12 hours (Per AWRs.) - (See C.5.)

27. **User Committee** - An advisory committee for each Shared Animal Facility made up of senior intramural scientists, IC Animal Program Director(s) and appropriate management

personnel from each IC represented in the facility to advise the Facility Veterinarian on matters of space, personnel, finance, and other matters as specified in the Intraagency Agreement between ICs of the Shared Animal Facility.

28. **Veterinarian -**

ANIMAL PROGRAM DIRECTOR: A Doctor of Veterinary Medicine with training or experience in laboratory animal science and medicine, who is supervised by, and receives delegated program authority from the Director or Scientific Director (via delegated authority from the Institutional Official) for all activities involving animals in an IC and is responsible for ensuring compliance with this policy, the Guide, the PHS Policy, and the AWRs. (The Animal Program Director serves as the "Attending Veterinarian" for the purposes of Animal Welfare Act interpretations.)

ATTENDING VETERINARIAN: The IC Animal Program Director or other veterinarian as delegated by the IC Animal Program Director. The Attending Veterinarian shall have the authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of ACU for all animals acquired by the IC and maintained in NIH facilities. Veterinary care is provided directly by the sponsoring IC in its own facilities. Veterinary care is provided in Central or Shared Animal Facilities by the supporting IC or in consultation with the sponsoring IC(s) as defined through written agreements. Such agreements, which may include Standard Operating Procedures, are approved by the IC Director or Scientific Director of the sponsoring IC and either the Director (or designee) of the ORS in VRP Central Animal Facilities, or by the Director or Scientific Director (or designee) of the Lead IC in Shared Animal Facilities. In all cases, the ORS Animal Program Director in a Central Animal Facility or the Animal Program Director of the Lead IC in a Shared Animal Facility must be delegated the authority to ensure timely adequate veterinary care and to oversee the adequacy of other aspects of ACU for all animals in the facility.

FACILITY VETERINARIAN: A Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who receives delegated authority from the Animal Program Director responsible for that facility. The Facility Veterinarian has the responsibility and authority to ensure timely adequate veterinary care to all animals housed in the facility. The Facility Veterinarian is responsible for ensuring compliance with all applicable regulations, guidelines and policies, and for maintaining AAALAC accreditable standards of the ACU program and facility. The Facility Veterinarian has the responsibility and authority to report any issue of non-compliance to the Animal Program Director responsible for that facility and to the supporting and sponsoring IC Animal Care and Use Committees.

D. APPLICABILITY: This policy is applicable to all NIH-conducted or supported intramural activities involving animals - except NCI at Frederick. All NIH components, contractors, or institutions with which NIH has collaborative or cooperative agreements are required to comply,

as applicable, with the AWRs, and other Federal statutes and regulations relating to animals.

E. POLICY: The NIH policy is that each investigator or person involved in the care or use of animals adhere to the Principles and applicable humane and ethical policies as established or referenced herein and maintain animals in accordance with the PHS Policy on Humane Care and Use of Laboratory Animals, the Guide and the AWRs. This policy shall include compliance with the provisions of NIH's intramural Institutional Assurance (A4149) on file with OLAW.

The NIH, as an institution, shall seek to maintain Full Accreditation of its animal program.

It is NIH policy that adequate veterinary care shall conform to the standards set forth in Adequate Veterinary Care by the American College of Laboratory Animal Medicine and as described in the AWRs.

The Director, OACU; IC Director or Scientific Director; IC-ACUC; IC Animal Program Director, Attending Veterinarian, and/or Facility Veterinarian are authorized to suspend any activity involving animals that have been previously approved if it is determined that the activity is not being conducted in accordance with the previously approved Animal Study Proposal or provisions of the AWRs, the Guide, or the Institution's Assurance. Suspension of an activity, however, will usually be initiated by the IC-ACUC following notification of the IC Director or Scientific Director.

NIH animal facilities have controlled access and need not be opened to the public, for a variety of reasons. Requests by outside individuals or groups to visit NIH animal facilities should be coordinated through the Office of Animal Care and Use, OIR, and the Division of Public Safety, ORS. The Office of Communications shall be notified, in writing, of all such requests.

F. RESPONSIBILITIES:

1. **The Deputy Director for Intramural Research (DDIR), NIH**, is responsible for ensuring compliance with this policy by all intramural ICs and others that use NIH facilities, and oversight of activities conducted under contract in support of intramural programs as performed in accordance with NIH Manual 3040-3 or other applicable acquisition regulations.

2. **The Director of the Office of Animal Care and Use**, has the authority delegated by the DDIR, for ensuring compliance of the Intramural ACU program with this NIH Manual, the AWRs, the PHS Policy, the provisions of the Guide and other applicable policies and regulations. The Director, OACU shall:

   a. Maintain the Institutional Assurance of compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals.

   b. Review semiannual IC ACU program evaluations for compliance with the Institutional

Assurance. Forward copies of the IC semiannual evaluations to the DDIR.

c. Maintain a list of IC-ACUC approved Animal Study Proposals.

d. Review and approve all animal facility construction and renovation plans.

e. Review and concur in all Central and Shared Animal Facility Intraagency Agreements addressing the management, or modifications thereto, of Central or Shared Animal Facilities, prior to their implementation.

f. Conduct unannounced site visits of ACU programs and facilities.

g. Act on behalf of the Institutional Official to implement appropriate corrective actions within the NIH ACU program.

3. **The Scientific Director, acting for the IC Director and the Director, NIH**, shall:

a. Be responsible for implementing and administering this policy for each IC that uses animals, and for taking appropriate action regarding recommendations from the IC Animal Program Director, or ACUC, or on requirements imposed by the Institutional Official.

b. Ensure participation in the Animal Exposure Surveillance Program (AESP), managed by the Occupational Medical Service, of the Division of Safety. Participation is a requirement for all personnel who work in animal facilities and who have significant contact with research animals or their tissues that have not been treated to assure freedom from pathogens, and others who work in areas where research animals are housed or used. This shall include, at a minimum, Principal Investigators (PI) and their staff who use animals in their research, and veterinarians and animal care staff members. Individuals electing not to participate in the AESP will be denied permission to participate in animal studies.

4. **Principal Investigators** shall:

a. Submit a completed and signed Animal Study Proposal, containing at a minimum the information contained on the format shown in Appendix 1, to the IC-ACUC Chair for review and approval before requesting animals or initiating animal studies. Each investigator shall include, as applicable, discussion of the consideration of alternatives to painful procedures and an assurance that the proposed studies are not unnecessarily duplicative, as required by the AWRs.

b. Complete the course, "Using Animals in Intramural Research: Guidelines for Principal Investigators" or participate in a comparable training experience approved by the Director, OACU, prior to approval of an Animal Study Proposal. This

requirement may be waived by the IC-ACUC until the next offering of the course.

c. Complete the triennial refresher training course for NIH Principal Investigators.

d. Ensure NIH personnel listed on an Animal Study Proposal complete the course "Using Animals in Intramural Research: Guidelines for Animal Users" or participate in a comparable training experience approved by the Director, OACU. This requirement may be waived by the IC-ACUC until the next offering of the course. Ensure these personnel receive subsequent training, as appropriate, to perform their assigned duties. Further ensure these personnel complete the triennial refresher training course for NIH animal users.

e. Comply with this policy, the Guide, the PHS Policy, and the AWRs.

f. Submit, in writing, for review and approval by the IC-ACUC any proposed significant changes from procedures described in an approved Animal Study Proposal. This shall include refinements and additions to animal activities developed during conduct of the procedures.

5. **The IC Animal Program Director** is responsible:

a. To his or her IC Director or Scientific Director for the day-to-day implementation of the Intramural ACU Program(s) within the IC.

b. For ensuring compliance with this policy, the Guide, the PHS Policy, and the AWRs in the animal program.

c. For ensuring that all animal care personnel demonstrate acceptable skill in assigned duties and performing techniques with the species of animal for which they are responsible.

6. **The IC Animal Program Director of a Lead IC for a Shared Animal Facility** is responsible to the Lead IC SD for ensuring compliance with this policy, the Guide, the PHS Policy, and the AWRs. This responsibility and authority may be delegated in whole or in part to the Facility Veterinarian of the Shared Animal Facility. The Facility veterinarian is advised by a User Committee and appointed by the Animal Program Director of the Lead IC, with concurrence of the Directors or Scientific Directors of the other ICs and the Director, OACU.

7. **The Facility Veterinarian**:

a. Ensures the provision of adequate veterinary care to all animals housed in the facility.

b. Ensures that the day-to-day operation of the animal facility is in compliance with this

policy.

c. Ensures that all animal care personnel demonstrate acceptable skill in assigned duties and in performing techniques with the species of animal for which they are responsible.

d. Ensures that daily facility operations, such as animal health care, husbandry and provision of supplies and equipment meet programmatic and regulatory requirements.

e. In Shared Animal Facilities, acts on recommendations from the User Committee and obtains concurrence from the Director(s) or Scientific Director(s) on matters of space, personnel and finances as specified in the Intraagency Agreement between ICs of the Shared Animal Facility.

f. In Central Animal Facilities, acts on directions from the Director, ORS on matters of space, personnel and finances as specified by Standard Operating Procedures or specifically in intraagency agreements with user ICs.

g. Shall work with the PIs and the PI's APD to ensure that refinements and/or additions to animal activities developed with investigative staff are communicated to the investigator's ACUC in a timely fashion.

8. **User Committee for Shared Animal Facilities** - Each Shared Animal Facility shall be advised by a User Committee with the following composition and responsibilities:

a. **Composition** - Members are appointed by the Director or Scientific Director of user ICs and include at least the following:

(1) Senior intramural scientist from each user IC;

(2) Administrative personnel from each user IC with delegated authority to obligate the ICs on matters of finance, personnel, space and other issues which may arise; and

(3) IC Animal Program Director(s), or their designees, from the user ICs.

Representation by each IC, including the Chair, and the number of members from each IC and the disciplines represented, shall be delineated in the Intraagency Agreement. The veterinarian serving as the Facility Veterinarian shall be a non-voting ex officio member.

A quorum of the Committee shall be defined as a majority of the Committee and a majority of the user ICs represented. Issues on which a vote is called shall require a majority of the quorum for passage.

b. **Responsibilities** -

(1) Advises the Facility Veterinarian and Director or Scientific Director of the Lead IC on matters of space, personnel and finance, or other matters, specified in the Intraagency Agreement required to support research in the facility and to ensure compliance with this policy, the Guide, the PHS Policy, and the AWRs.

(2) Submits, in writing, issues on which a minority opinion is filed to the Lead IC Director or Scientific Director. The Director or Scientific Director of the Lead IC, in consultation with the Directors or Scientific Directors of the other user ICs and the Director, OACU, will provide written resolution of the issue to the DDIR within 30 calendar days.

9. **The Animal Program Directors Committee** shall have the following composition and responsibilities:

a. **Composition** - The Committee shall consist of the Animal Program Director(s) in each IC. The Chair shall be elected from the membership.

b. **Responsibilities** -

(1) The Committee shall meet monthly or as needed to fulfill its responsibilities and provide advice and guidance to the Director, Office of Animal Care and Use.

(2) The Committee shall be responsible for reviewing veterinary operational issues which affect the overall NIH ACU program.

(3) Recommendations from this Committee shall be presented to the NIH-ARAC and/or the DDIR, as appropriate, for action.

10. **The Animal Program Advisory Committee (APAC)**, a subcommittee of the Animal Program Directors Committee, shall have the following composition and responsibilities:

a. **Composition** - The Committee shall consist of facility veterinarians and facility managers from the ICs and ORS and other NIH central service providers. The APAC shall be chaired by the Deputy Director, OACU.

b. **Responsibilities** -

(1) The Committee shall meet at least quarterly and provide advice and guidance to the Animal Program Directors Committee and the Director, Office of Animal Care and Use.

(2) The Committee shall be responsible for reviewing facility operational issues which affect the overall NIH ACU program.

11. **Each IC that uses research animals in its intramural program shall maintain an Animal Care and Use Committee (IC-ACUC)** with the following composition and responsibilities:

a. **Composition** - Not more than three members shall be from the same office, laboratory or branch of the facility (IC). The Chair and members are appointed by the IC Director or Scientific Director, per the authority delegated from the Director, NIH. Each IC-ACUC is composed of at least five individuals and includes 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 within the IC;

(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);

(4) One individual who is not affiliated with the Federal government and not affiliated with the NIH, in any way other than as a member of the IC-ACUC, and is not a member of the immediate family of a person who is affiliated with the Institution. This person will provide representation for general community interests in the proper care and treatment of animals; and

(5) The ombudsman, see paragraph F.12.a.(6), shall serve as an ex- officio member of all ACUCs. The ombudsman is not obligated to attend all meetings, and is not counted in determining if a quorum is present.

b. **Responsibilities** - The IC-ACUCs shall:

(1) Review ACU programs and inspect all IC facilities (including satellite facilities, animal study areas, and areas in which survival surgical manipulations are performed) at least semiannually using the Guide and the AWRs as a basis for evaluation. The Lead IC-ACUC shall be responsible for the semiannual evaluation of Shared Animal Facilities. The ORS-ACUC shall be responsible for semiannual evaluations of Central Animal Facilities. At least two members of the ACUC of each IC housing animals in Shared or Central Animal Facilities shall review the animals and the animal activities of its investigators in those facilities at least semiannually.

(2) Prepare written reports of the IC-ACUC semiannual evaluations conducted as

required by the PHS Policy and the AWRs and submit the reports to the DDIR/OACU in April and October, with a copy to the IC Director or Scientific Director. The reports must contain a description of the nature and extent of each IC's adherence to the Guide, the PHS Policy, and the AWRs, must identify specifically any departures from the provisions of the Guide, the PHS Policy, and the AWRs; and must state reasons for each departure. In accordance with the PHS Policy and the AWRs, the reports must distinguish significant deficiencies from minor deficiencies and contain a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one which, in the judgement of the IC-ACUC, and IC Director or Scientific Director, and/or the DDIR/OACU is or may be a threat to the health or safety of the animals. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IC-ACUC, through the Director, OACU, to the DDIR. The DDIR shall report such instances to OLAW.

No Committee member wishing to participate in any evaluation may be excluded except for reasons of conflict of interest. The IC-ACUC may use subcommittees composed of at least two Committee members and may invite ad hoc consultants to assist in conducting the evaluations. The reports shall be reviewed and signed by a majority of the IC-ACUC members and must include any minority views.

The Lead IC-ACUC shall be responsible for the written report of the semiannual evaluation of the ACU program and facilities in Shared Animal Facilities.

The ORS-ACUC shall be responsible for the written report of the semiannual evaluation of the ACU program and facilities of the Central Animal Facilities.

(3) Review all IC Animal Study Proposals related to the care and use of animals (to include requests for the use of satellite facilities) to ensure adherence to the humane and ethical principles for use of animals as outlined in the Guide and the AWRs . The Animal Study Proposal is to be used for this purpose. Animal Study Proposal numbers are to be recorded in the minutes of the IC-ACUC, together with significant aspects of the review and disposition. Meeting minutes and reports are subject to Freedom of Information Act requests.

(4) In April and October, submit to the Director, OACU, a listing of currently active approved Animal Study Proposals with the following information: Proposal No., Title, Principal Investigator, and Date Approved.

(5) Notify the investigators and the institution, i.e., the IC Director or Scientific Director, in writing, of decisions to approve or withhold approval of those

sections of Animal Study Proposals related to the care and use of animals, or of modifications required to secure IC-ACUC approval as set forth in the PHS Policy and the AWRs. Copies of approved Animal Study Proposals and all approved modifications to existing Animal Study Proposals shall be provided to Facility management for review and acceptance prior to initiation of the study in the facility(ies) where the animals included in such studies will be housed and/or used.

(6) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy and the AWRs.

(7) Be authorized to suspend an activity involving animals that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the AWRs, the Guide, the Institution's Assurance, or the PHS Policy. The IC-ACUC may suspend an activity only after a review of the matter at a convened meeting of a quorum of the IC-ACUC and with the suspension vote of a majority of the quorum present. If the IC-ACUC suspends an activity involving animals, the IC Director or Scientific Director in consultation with the IC-ACUC, shall review the reasons for suspension, and recommend appropriate action to the DDIR for implementation. The DDIR will review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW as required by the PHS Policy.

(8) Review all proposed methods of euthanasia and consider waivers for those not recommended by the American Veterinary Medical Association (AVMA) Panel on Euthanasia as required by the PHS Policy and the AWRs. Waivers from the AVMA recommendations are authorized by the ACUC only for scientific reasons. They are issued in writing and filed with the ACUC Chair, either separately or as a part of the Animal Study Proposal.

(9) Advise investigators regarding animal care and use as requested by IC investigators, required by the IC Director or Scientific Director or Institutional Official, or as recommended by the NIH-ARAC. This shall include ensuring that all ACU program activities under their purview are performed with consideration of current ARAC Guidelines.

(10) Remain cognizant of animal care and use practices of IC investigators and advise the IC Director or Scientific Director and the Institutional Official of significant changes from those described in their most recent project review. Considering the recommendations contained in the NIH-ARAC Guidelines, this is to include the practices conducted in shared, central and satellite facilities.

(11) Advise the NIH-ARAC and the OACU of unresolved deficiencies in any aspect of the IC program of animal care and use. ORS and Lead ICs shall similarly advise of unresolved deficiencies in Central or Shared Animal Facilities respectively. These deficiencies will, in turn, be reported to the Institutional Official (DDIR). Any unresolved significant deficiencies shall be reported to OLAW, as required by the PHS Policy.

(12) Hold meetings monthly or as needed to fulfill its responsibilities, in which a majority of the IC-ACUC members attend. The Chair[1] ensures that all members are notified of these meetings in a timely fashion, provides copies of minutes to the IC Director or Scientific Director and the OACU, and maintains a file of all minutes, memoranda, waivers, and project review documents that will be disposed of in accordance with approved records disposal schedules. Minutes, records of attendance and project reviews will be maintained in accordance with the NIH Manual 1743, Keeping and Destroying Records, Appendix 1, 1100-H-2 following termination of the research.

(13) Prepare the IC's "Annual Report of Research Facility" as required by the United States Department of Agriculture (USDA) and submit it to the OACU in conjunction with the November NIH-ARAC meeting. The OACU will prepare the composite NIH report and submit it to the USDA. For further information contact the OACU, OD, NIH, at 301-496-5424.

(14) Identify training needs for intramural staff who work with laboratory animals, communicate those needs to the Training Coordinator, Laboratory Animal Care and Use, OACU, and assist the Coordinator with the development of the appropriate courses.

(15) Ensure new ACUC members complete ACUC Member training provided by OACU.

(16) Advise the IC Director or Scientific Director regarding the training of professional and technical staff in animal care and use.

(17) Advise the IC Director or Scientific Director concerning newly proposed or enacted legislation, policies, and guidelines regarding laboratory animals, including recommending responses to proposals, and implementing enacted procedures.

(18) Review, and, if warranted, investigate concerns involving the care and use of

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[1] or Executive Secretary, where appropriate.

animals within the research facility (IC) resulting from complaints received and from reports of noncompliance received from laboratory or research facility personnel, employees, or the public. All instances of noncompliance shall be reported to DDIR/OACU to effect appropriate Institutional communications with OLAW.

(19) Conduct continuing reviews of activities covered by the PHS Policy and the AWRs (including exemptions to plans for exercise for dogs and environmental enrichment for nonhuman primates) at appropriate intervals, but not less than annually.

12. **The NIH Animal Research Advisory Committee (NIH-ARAC)** is established by the DDIR, who appoints its Chair, Executive Secretary, veterinarian, non-scientist, ombudsman, and the non-affiliated member. The Executive Secretary and staff support are provided by the Office of Animal Care and Use, OD, NIH.

a. **Composition** - The NIH-ARAC is composed of full-time Federal Government employees and includes at least:

(1) The Chair from each IC-ACUC. The Vice Chair shall serve as the alternate member from each IC. APDs shall not serve as the alternate member from each IC but should attend the meetings.

(2) One Doctor of Veterinary Medicine with training or experience in laboratory animal science and medicine who has delegated oversight responsibility for compliance of activities involving animals at NIH.

(3) One practicing scientist experienced in research involving animals.

(4) One member whose primary concerns are in a non-scientific area.

(5) One individual who is not affiliated with NIH, in any way other than as a member of the NIH-ARAC, and is not a member of the immediate family of a person who is affiliated with NIH. This person will provide representation for general community interests in the proper care and treatment of animals.

(6) An ombudsman, appointed by the DDIR, to receive, review, and assure an appropriate response to complaints concerning the care and use of animals in the intramural program. The duties and responsibilities of the ombudsman are detailed in the NIH Animal Research Advisory Committee (NIH-ARAC) Guidelines.

b. **Responsibilities** - The NIH-ARAC:

(1) Meets at monthly intervals or as needed to advise the DDIR on the Institution's program for humane care and use of animals and to support the Institution's conformance to Guide recommendations and this policy. The Chair[2] ensures that all members are notified of these meetings in a timely fashion and provides copies of minutes to the DDIR. The Executive Secretary maintains file copies of all meetings, minutes and attendance, memoranda, and activities of the Committee.

(2) Reviews IC and/or trans-NIH concerns involving the care and use of animals at NIH following investigation, deliberation, and closure by the IC ACUC(s).

(3) Makes written recommendations to the DDIR, NIH, regarding any aspect of the Intramural ACU program, facilities, or personnel training which needs improvement or change.

(4) Serves in an advisory role to the NIH Director and the DDIR in all matters involving animal care and research use.

(5) Identifies trans-NIH training needs for intramural staff who work with laboratory animals, and assists the Training Coordinator, Laboratory Animal Care and Use, with the development of the appropriate courses.

(6) Provides copies of its minutes to the DDIR and maintains minutes and records of attendance, in accordance with the NIH Manual 1743, Keeping and Destroying Records, Appendix 1, 1100-H-2.

G. TRANSPORTATION OF ANIMALS: Transportation of experimental animals on NIH property, either between or within buildings or facilities, to or from commercial carriers, or in any other manner shall be in accordance with NIH-ARAC Guidelines. If a vehicle is used, it must be properly designed for the transportation of animals.

H. TRANSFER OF ANIMALS: The transfer of animals for research purposes, pursuant to section 301 of the Public Health Service Act, shall be in conformance with the provisions of the Animal Transfer Agreement contained in the ARAC Guidelines, or as specified in other binding agreements, such as Material Transfer Agreements or Cooperative Research and Development Agreements.

I. CONTROLLED SUBSTANCES: The acquisition of controlled substances for use in animals shall be in conformance with NIH Manual 1345, Handling and Safeguarding of Controlled Substances for Nonhuman Use.

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[2] or Executive Secretary, where appropriate.

J. RECORDS RETENTION and DISPOSAL: All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records, Appendix 1, NIH Records Control Schedule," Items: 1100-H-2, committee records; 3000-C, VRP, ORS records; and 3000-G-2-a, biomedical research protocol records related to animal use.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

K. MANAGEMENT CONTROLS: The purpose of this manual is to establish responsibility for humane care and use of animals within the intramural program of NIH.

1. **Office Responsible for Reviewing Management Controls Relative to this Chapter:** Office of Animal Care and Use and the Office of Intramural Research.

2. **Frequency of Review (in years):** Ongoing; at least annually.

3. **Method of Review:** Alternative Review. The IC Directors or Scientific Directors participate in the Biennial Intramural Self Assessment of Management Controls, through completion of a set of comprehensive checklists of questions. This process is managed by the Office of Intramural Research.

   The Intramural Program must make annual reports to both the United States Department of Agriculture and the PHS Office of Laboratory Animal Welfare (OLAW.) These agencies have regulatory authorities over the NIH IRP ACU program. Per the PHS Policy, instances of significant noncompliance are required to be reported to OLAW, In addition, the Association for Assessment and Accreditation of Laboratory Animal Care International performs triennial peer review site visits to all NIH components who use animals in their IRP programs.

4. **Review Reports** are sent to: the Deputy Director for Intramural Research.

ANIMAL CARE AND USE IN THE INTRAMURAL PROGRAM

Leave Blank
PROPOSAL # _____

APPROVAL DATE _____

EXPIRATION DATE _____

NATIONAL INSTITUTES OF HEALTH

ANIMAL STUDY PROPOSAL

(See NIH Manual 3040-2)

PLEASE TYPE

A. ADMINISTRATIVE DATA:

Institute or Center_____

Principal Investigator_____

Building/Room_____E-Mail_____Telephone_____FAX_____

Division, Laboratory, or Branch_____

Project Title_____

_____

Initial Submission [ ] Renewal [ ] or Modification [ ] of Proposal Number_____

List the names of all individuals authorized to conduct procedures involving animals under this proposal and identify key personnel (i.e., Co-investigator(s)):

B. ANIMAL REQUIREMENTS:

Species_____Age/Weight/Size_____Sex_____

Stock or Strain_____

Source(s)_____Holding Location(s)_____

Animal Procedure Location(s)_____

Number of Animals:

_____ _____ _____ =_____
Year 1 Year 2 Year 3 TOTAL

ANIMAL CARE AND USE IN THE INTRAMURAL PROGRAM

C. TRANSPORTATION: Transportation of animals must conform to all NIH and Facility guidelines/policies. If animals will be transported between facilities, describe the methods and containment to be utilized. If animals will be transported within the Clinical Center, also include the route and elevator(s) to be utilized.

D. STUDY OBJECTIVES: Briefly explain in non-technical terms the aim of the study and how the study may benefit human or animal health or advance scientific understanding of biological processes.

E. RATIONALE FOR ANIMAL USE: 1) Explain your rationale for animal use. 2) Justify the appropriateness of the species selected. 3) Justify the number of animals to be used. **(Use additional sheets if necessary.)**

F. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES: Briefly explain the experimental design and specify all animal procedures. This description should allow the ACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study. Specifically address the following:
(Use additional sheets if necessary.)

- **Injections or Inoculations** (substances, e.g., infectious agents, adjuvants, etc.; dose, sites, volume, route, and schedules)
- **Blood Withdrawals** (volume, frequency, withdrawal sites, and methodology)
- **Non-Survival Surgical Procedures** (Provide details of survival surgical procedures in Section G.)
- **Radiation** (dosage and schedule)
- **Methods of Restraint** (e.g., restraint chairs, collars, vests, harnesses, slings, etc.)
- **Animal Identification Methods** (e.g., ear tags, tattoos, collar, cage card, etc.)
- **Other Procedures** (e.g., survival studies, tail biopsies, etc.)
- **Resultant Effects**, if any, the animals are expected to experience (e.g., pain or distress, ascites production, etc.)
- **Experimental Endpoint Criteria** (i.e., tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity) must be specified when the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expected to cause significant symptomatology or are potentially lethal. List the criteria to be used to determine when euthanasia is to be performed. Death as an endpoint must always be scientifically justified.

ANIMAL CARE AND USE IN THE INTRAMURAL PROGRAM

G. SURVIVAL SURGERY - If proposed, complete the following:

1. Identify and describe the surgical procedure(s) to be performed. Include the aseptic methods to be utilized. **(Use additional sheets if necessary)**:

2. Who will perform surgery and what are their qualifications and/or experience?:

3. Where will surgery be performed, Building and Room?_____

4. Describe post-operative care required, including consideration of the use of post-operative analgesics, and identify the responsible individual:

5. Has major survival surgery been performed on any animal prior to being placed on this study? Y/N___ If yes, please explain:

6. Will more than one major survival surgery be performed on an animal while on this study? Y/N._____. If yes, please justify:

ANIMAL CARE AND USE IN THE INTRAMURAL PROGRAM

H. PAIN OR DISTRESS CATEGORY - ***The ACUC is responsible for applying U.S. Government Principle IV. contained in Appendix 3: 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.*** Check the appropriate category(ies)and indicate the approximate number of animals in each. Sum(s) should equal total from Section B.

IF ANIMALS ARE INDICATED IN COLUMN E, A SCIENTIFIC JUSTIFICATION IS REQUIRED TO EXPLAIN WHY THE USE OF ANESTHETICS, ANALGESICS, SEDATIVES OR TRANQUILIZERS DURING AND/OR FOLLOWING PAINFUL OR DISTRESSFUL PROCEDURES IS CONTRAINDICATED. PLEASE COMPLETE THE EXPLANATION FOR COLUMN E LISTINGS FORM AT THE END OF THIS DOCUMENT. THIS FORM WILL ACCOMPANY THE NIH ANNUAL REPORT TO THE USDA. NOTE: THIS COLUMN E FORM, AND ANY ATTACHMENTS, e.g., THE ASP, ARE SUBJECT TO THE FREEDOM OF INFORMATION ACT.

	NUMBER OF ANIMALS USED EACH YEAR		
	Year 1	Year 2	Year 3
[ ] **USDA Column C** - Minimal, Transient, or No Pain or Distress	_____	_____	_____
[ ] **USDA Column D** - Pain or Distress Relieved By Appropriate Measures	_____	_____	_____
[ ] **USDA Column E** - Unrelieved Pain or Distress	_____	_____	_____

Describe your consideration of alternatives to procedures listed for Column D and E that may cause more than momentary or slight pain or distress to the animals, and your determination that alternatives were not available. [Note: Principal investigators must certify in paragraph N.5. that no valid alternative was identified to any described procedures which may cause more than momentary pain or distress, whether it is relieved or not.] Delineate the methods and sources used in the search below. **Database references must include databases (2 or more) searched, the date of the search, period covered, and keywords used:**

I. ANESTHESIA, ANALGESIA, TRANQUILIZATION - For animals indicated in Section H, Column D, specify the anesthetics, analgesics, sedatives or tranquilizers that are to be used. Include the name of the agent(s), the dosage, route and schedule of administration.

J. METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY: Indicate the proposed method, and if a chemical agent is used, specify the dosage and route of administration. If the method(s) of euthanasia include those not recommended by the AVMA Panel Report on Euthanasia, provide justification why such methods must be used. Indicate the method of carcass disposal if not as MPW.

ANIMAL CARE AND USE IN THE INTRAMURAL PROGRAM

K. HAZARDOUS AGENTS: Use of hazardous agents requires the approval of an IC safety specialist. Registration Documents for the use of recombinant DNA or potential human pathogens may be attached at the discretion of the ACUC.

	YES	NO	List Agents and Registration Document Number (If Applicable)
1. Radionuclides			
2. Biological Agent			
3. Hazardous Chemical or Drugs			
4. Recombinant DNA			

Study conducted at Animal Biosafety Level: _____

Describe the practices and procedures required for the safe handling and disposal of contaminated animals and material associated with this study. Use of volatile anesthetics requires a description of scavenging methods used. Also describe methods for removal of radioactive waste and, if applicable, the monitoring of radioactivity.

Additional safety considerations:

L. BIOLOGICAL MATERIAL/ANIMAL PRODUCTS FOR USE IN ANIMALS (e.g., cell lines, antiserum, etc.):

1. Specify Material_____
2. Source_____Material Sterile or Attenuated_____Yes_____No
3. If derived from rodents, has the material been MAP/RAP/HAP tested? _____Yes (Attach copy of results) No_____
4. I certify that the MAP/RAP/HAP tested materials to be used have not been passed through rodent species outside of the animal facility in question and/or the material is derived from the original MAP tested sample. To the best of my knowledge the material remains uncontaminated with rodent pathogens.

_____**Initials of Principal Investigator.**

ANIMAL CARE AND USE IN THE INTRAMURAL PROGRAM

M. SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY - List any special housing, equipment, animal care (i.e., special caging, water, feed, or waste disposal, etc.). Include justification for exemption from participation in the environmental enrichment plan for nonhuman primates or exercise for dogs.

N. PRINCIPAL INVESTIGATOR CERTIFICATIONS:

1. I certify that I have attended an approved NIH investigator training course.
   Year of Course Attendance:_____Location_____
   Year(s) of Refresher Training: _____

2. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.

3. I certify that all individuals working on this proposal who have significant animal contact are participating in the NIH Animal Exposure Surveillance Program.

4. I certify that the individuals listed in Section A are authorized to conduct procedures involving animals under this proposal have attended the course "Using Animals in Intramural Research: Guidelines for Animal Users" and will complete refresher training as required, and received training in the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary); procedures for reporting animal welfare concerns.

5. **FOR ALL COLUMN D AND COLUMN E PROPOSALS (see section H):** I certify that I have reviewed the pertinent scientific literature and the sources and/or databases (2 or more) **as noted in paragraph H,** and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.

6. I will obtain approval from the ACUC before initiating any significant changes in this study.

Principal Investigator: Signature_____Date_____

ANIMAL CARE AND USE IN THE INTRAMURAL PROGRAM

O. CONCURRENCES: PROPOSAL NUMBER _____ (LEAVE BLANK)

Laboratory/Branch Chief certification of review and approval on the basis of scientific merit. Scientific Director's signature required for proposals submitted by a Laboratory or Branch Chief.

Name_____Signature_____Date_____

Safety Representative certification of review and concurrence. (Required of all studies utilizing hazardous agents.)

Name_____Signature_____Date_____

Facility Manager certification of resource capability in the indicated facility to support the proposed study.

Facility_____Name_____Signature_____Date_____

Facility_____Name_____Signature_____Date_____

Facility_____Name_____Signature_____Date_____

Facility_____Name_____Signature_____Date_____

COMMENTS:

Facility Veterinarian certification of review.

Name_____Signature _____Date_____

Attending Veterinarian Certification of Review.

Name_____Signature_____Date_____

P. FINAL APPROVAL:

Certification of review and approval by the _____ Animal Care and Use Committee Chairperson.

Chairperson_____Signature_____Date_____

ANIMAL CARE AND USE IN THE INTRAMURAL PROGRAM

Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

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1. **Registration Number: 51-F-0016**

2. **Number of animals used under Column E conditions in this study. _____**

3. **Species (common name) of animals used in this study. _____**

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected.**

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.**

Information below will NOT be forwarded to USDA as part of the Annual Report

IC _____ ASP Number _____ ASP Title_____

Signature of Principal Investigator_____Date _____

ANIMAL CARE AND USE IN THE INTRAMURAL PROGRAM

REFERENCES

For information about any of the references in this chapter contact your IC ACUC Chairperson.

A. Laws:

1. Animal Welfare Act (7 U.S.C. 2131 et. seq.).
2. The Endangered Species Act of 1973 (16 U.S.C. 1531 et. seq.).
3. The Public Health Services Act, as amended (42 U.S.C. 283e, 289d).

B. Regulations:

1. Animal Welfare, 9 CFR, Parts 1, 2, and 3.
2. Good Laboratory Practice for Nonclinical Laboratory Studies (Title 21, CFR, Part 58).
3. Procurements Involving the Use of Laboratory Animals (Federal Acquisition Regulations, Title 48 CFR, Chapter 3, Part PHS 352.280-2) (10-1-00 Edition).

C. Policies:

1. Guide for the Care and Use of Laboratory Animals, NRC 1996.
2. PHS Policy on Humane Care and Use of Laboratory Animals, *Revised* September, 1986. Reprinted October 2000.
3. NIH Animal Research Advisory Committee Guidelines, NIH-ARAC, January 2002, or as revised.
4. Report of the AVMA Panel on Euthanasia, JAVMA 218, 669-696, March 1, 2001.
5. Biosafety in Microbiological and Biomedical Laboratories, May, 1999. HHS Publication No. (CDC) 93-8395.
6. The National Institutes of Health Radiation Safety Guide, August 1996.
7. Radiation Safety for Animal Handlers, Radiation Safety Branch, Division of Safety.
8. Adequate Veterinary Care, Report of the American College of Laboratory Animal Medicine, 1996.

ANIMAL CARE AND USE IN THE INTRAMURAL PROGRAM

D. <u>Other NIH Manual Chapters</u>:

1. NIH Manual 1340-1 Permits for Import or Export of Biological Materials.

2. NIH Manual 6307-3, Special Clearance and Other Acquisition Procedures. Appendix 1.

3. NIH Manual Chapter 3043-1, Introduction of Rodents and Rodent Products.

4. NIH Manual Chapter 1165, Agency Agreements.

5. NIH Manual Chapter 1130, Program, General 31, NIH Intramural Animal Care and Use Program

6. NIH Manual Chapter 1345, Handling and Safeguarding of Controlled Substances for Nonhuman Use

ANIMAL CARE AND USE IN THE INTRAMURAL PROGRAM

Interagency Research Animal Committee's

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[1].

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 in 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.

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[1] 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 Research Council.

ANIMAL CARE AND USE IN THE INTRAMURAL PROGRAM

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 research committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

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