

# NIH Policy Manual

## 3040-2 - Animal Care and Use in The Intramural Research Program

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### Transmittal Notice

- 1. Explanation of Material Transmitted:** This revised chapter establishes responsibility for humane care and use of animals within the intramural program of NIH. Minor changes have been provided to the main document to include further defining individual responsibilities, and the Animal Study Proposal form has streamlined needed information for some sections. **Partial Revision Date 03/18/2022:** Revised Section B. Scope for clarity, updated Section F. Responsibilities for IC-ACUC to revise animal activities frequency of required reviews from annually to triennially (see F.13.b.xix) based on revisions to [9 CFR 2.31\(d\)\(5\)](#), and corrected links, references, and citations.
- 2. Filing Instructions:**

- **Remove:** NIH Manual Chapter 3040-2, dated 02/27/2008.
- **Insert:** NIH Manual Chapter 3040-2, dated 04/22/2014; Partial Revision: 03/18/2022

**PLEASE NOTE:** For information on:

- Content of this chapter, contact the issuing office listed above.
- NIH Policy Manual, contact the Division of Compliance Management, OMA, on 301-496-4606 or: <https://oma.od.nih.gov/DMS/Pages/Manual-Chapters.aspx>.

### 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). NIH is the steward of medical and behavioral research for the Nation. NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life and reduce illness and disability. The IRP conducts distinctive, high-risk, high-impact laboratory, clinical, and population-based research in a unique environment, where it also trains a diverse population of outstanding future researchers to conduct high-impact peer-reviewed research.

## **B. Scope**

This policy applies to NIH personnel including federal employees, contractors, trainees, students, volunteers, guest researchers who are involved in the maintenance, research, or care of animals in the Intramural Research Program at NIH facilities. 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 Animal Welfare Regulations (AWR), Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) and other Federal statutes and regulations relating to animals.

## **C. Policy**

The NIH intramural policy is that each investigator or person involved in the care or use of animals adhere to the U. S. Government Principles and applicable humane and ethical policies as established or referenced herein and maintain animals in accordance with the PHS Policy, the Guide for the Care and Use of Laboratory Animals (Guide) and the AWRs. This policy shall include compliance with the provisions of NIH Intramural Research Program Institutional Assurance ID: D16-00602 (formally A4149-01) on file with the Office of Laboratory Animal Welfare (OLAW).

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

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 Institutional Official's (IO) policy memo: "[Communicating Animal Care and Use Concerns within the NIH Intramural Research Program](#)" is prominently displayed in all primary and satellite animal facilities and other routinely used animal procedure areas. This memo strongly encourages anyone with an animal welfare concern to communicate that concern and it provides a range of individuals they can approach. The memo also provides the Office of Animal Care and Use (OACU) contact information as an avenue for anonymous reporting to the OACU Director.

The Animal Research Advisory Committee (ARAC) [Guidelines for Responding to Animal Care & Use Complaints from Outside NIH](#) describe the role of the ARAC Ombudsman for assisting with animal welfare concerns that come from outside the NIH community or that cross multiple IC Animal Care Use ACU programs.

The Institutional Official; Director, Office of Animal Care and Use (OACU); Scientific Director (SD); IC Animal Care and Use Committee (ACUC); ACUC Chair, IC Animal Program Director (APD), Attending Veterinarian, and/or Facility Veterinarian are authorized to temporarily stop any procedure involving animals if it is determined that the activity is not being conducted in accordance with the previously approved Animal Study Proposal (ASP) or

provisions of the PHS Policy, AWRs, the Guide, or the Institutional Assurance. The temporary cessation of procedure(s) will be immediate, but must be brought to the IC-ACUC for review. (See F.13.b. IC-ACUC Responsibilities)

NIH intramural 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 can be coordinated through OACU or by directly contacting the IC Animal Program Director.

Animal welfare and the integrity of research findings, rather than cost alone, should be the primary factors in decisions related to assuring compliance with the recommendations in the Guide. See U.S. Government Principles, PHS Policy and the Guide to define the minimum standards (“musts”) and performance standards (“shoulds”) that OLAW expects of Assured institutions. The IRP and individual ACUCs make value judgments and set priorities that consider transactional costs (resources, personnel, equipment, material, productivity, administration, training, investigator/committee/animal program staff time or effort) while meeting the animal welfare standards.

## D. References

[See Appendix 1.](#)

## E. Definitions

1. **Accreditation** - The recognition by the [Association for Assessment and Accreditation of Laboratory Animal Care International \(AAALAC International\)](#) that the animal facilities and management practices of a research institution are in accordance with the *Guide for the Care and Use of Laboratory Animals*. (See E. 13. below)
2. **Adequate Veterinary Care** - The standards set forth in Adequate Veterinary Care by the American College of Laboratory Animal Medicine and the 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.
4. **Animal Exposure Program (AEP)** - That portion of the NIH occupational health program, managed by the Occupational Medical Service (OMS), Division of Occupational Health and Safety (DOHS), Office of Scientific Resources (SR), Office of Research Services (ORS), Office of Management (OM), specifically designed for all NIH personnel who work in animal facilities or who have 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. Individuals electing not to participate in the AEP may be denied permission to participate in animal studies.

Institute/Center (IC) (See E.14.) programs outside the metropolitan Washington DC area, e.g. Office of Research Infrastructure Programs’ (ORIP) 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.
  1. **CENTRAL ANIMAL FACILITY**: An animal facility managed by the Division of Veterinary Resources (DVR), SR, ORS, and utilized by more than one Institute/Center (IC).
  2. **SATELLITE FACILITY** - 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]
  3. **SHARED ANIMAL FACILITY**: An animal facility shared by more than one IC and managed by a Lead IC.
  4. **STUDY AREA**: Any building room, area, enclosure or other containment outside of a core facility or centrally designated or managed area in which regulated animal species 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 E.15.) The Deputy Director for Intramural Research shall appoint the Chair, Executive Secretary and additional members.
7. **ARAC Guidelines** - Guidelines developed and approved by the ARAC to interpret regulations and policy and establish best practices among ICs that, when applied, assure consistency of practice.
8. **Animal Study Proposal (ASP)** - The document completed by a Principal Investigator and submitted to the Chair, IC ACUC for review and approval prior to the acquisition of animals or initiation of the study. (See [IO Policy Memo](#))
9. **Animal Program Directors (APD) Committee** – the Animal Program Directors Committee includes the APD from each IC animal care program. The Chair of the Committee is elected from their ranks.
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. **Animal User** - A scientist, technician, animal care staff member, or other individual listed on an ASP who may conduct animal procedures described in the ASP.
12. **Facility Management** - The Facility Veterinarian and Facility Manager(s), operating under the authority of the Animal Program Director, responsible for the day-to-day management of NIH animal facilities.
13. **Guide** - The National Research Council's *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.
14. **Institute/Center (IC)** - For the purposes of this Policy Manual and the NIH IRP Animal Care and Use (ACU) program, each IC is directed by a single Institute Director; by delegated authority the IC's intramural research program is directed by one or more individual program director, e.g. Scientific Director; when research with animals is conducted by staff within that IC there is one IC-ACUC (See E.15.) and one Animal

Program Director (APD) (See E.28.). Exceptions are noted within the NIAID, and ORIP as follows: a) the NIAID has four intramural components, each with an ACUC and three with a separate APD - those components include the NIAID Division of Intramural Research and the Rocky Mountain Laboratories which are directed by one NIAID Scientific Director and one Animal Program Director, the NIAID Division of Clinical Research, directed by the Director of Clinical Research, and the NIAID Vaccine Research Center, which is directed by a separate Scientific Director; b) the ORIP does not have an intramural component, however, through a Memorandum of Understanding, the ORIP'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 E.17.)

15. **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/IO per the IC Director), by the 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 Animal Study Proposals.
16. **Institution** - The NIH intramural research program including facilities in Bethesda, other NIH (owned or leased) 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 research program.
17. **Institutional Assurance** - The IRP 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.
18. **Institutional Official (IO)** - 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. ([See Appendix 1](#))
19. **Intra-agency Agreement (IAA)** - 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 and should adhere to the standards provided in [NIH Manual 1165: Agency Agreements](#). 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 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 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.

20. **Lead Institute** - The user IC, which other user ICs authorize through an intra-agency agreement, to manage a Shared Animal Facility.
21. **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 and maintain Full Accreditation with AAALAC. This authority is exercised by the Director, OACU.
22. **PHS Policy** - Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, Revised as of August 2002, or subsequent editions.
23. **Principles** - U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training
24. **Principal Investigator (PI)** - 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.
25. **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 euthanizing the animals.
26. **Responsible Investigator (RI)** – The RI is a scientist who is an NIH employee with knowledge and authority to oversee Animal Study Proposal activities conducted by or on behalf of a Principal Investigator (PI) who is not an NIH employee.

The Responsible Investigator signs the ASP and by signing accepts responsibility to ensure compliance with this NIH Policy Manual, the Guide, the PHS Policy and the AWRs. The RI signs the ASP in addition to the PI and the Lab/Branch Chief when the PI is a trainee, Adjunct Investigator or Contract Employee. When the contract employee is the PI, the RI provides input to the project officer and/or contracting officer for issues related to animal care and use. When the PI is a Postdoctoral Fellow or Adjunct Investigator, the RI may serve as the mentor or supervisor of the PI. If not the mentor or supervisor, the RI provides input to the PI's mentor or supervisor for issues related to animal care and use.

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 Facility Management on matters of space, personnel, finance, and other matters as specified in the Intra-agency Agreement between ICs of the Shared Animal Facility.
28. **Veterinarian**

1. **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 Scientific Director (per delegated authority via the IC Director 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, the AWRs, and for maintaining AAALAC accreditable standards of the ACU program and facility(ies). (The Animal Program Director serves as the "Attending Veterinarian" for the purposes of Animal Welfare Act interpretations.)

2. **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 under their oversight [see Facility Veterinarian]. Veterinary care is provided directly by the IC in its own facilities. Veterinary care is provided in Central facilities by ORS. Veterinary care is provided in Shared Animal Facilities by the Lead IC (see E.5. above) or in consultation with the user IC(s) as defined through written agreements. Such agreements, which may include Standard Operating Procedures, are approved by the Scientific Director of the user IC and either the Director (or designee) of the ORS in DVR Central Animal Facilities, or by the 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.
3. **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 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.

## **F. Responsibilities**

1. **The Deputy Director for Intramural Research (DDIR), NIH**, as the Institutional Official (IO), 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 IO, for ensuring compliance of the Intramural ACU program with this NIH Policy

Manual, the AWRs, the PHS Policy, the provisions of the Guide and other applicable policies and regulations (see references). 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. This shall include preparation of Assurance documents, correspondence, and reports for the Office of Laboratory Animal Welfare, Office of Extramural Research, NIH.
- b. Review semiannual IC ACU program evaluations for compliance with the Institutional Assurance, and forward copies of the IC semiannual evaluations to the IO.
- c. Designate OACU staff members to serve as (non-voting) observers on the IRP IC ACUCs.
- d. Review animal facility construction and renovation plans to facilitate regulatory and compliance requirements.
- e. Review and concur with, prior to implementation, any IAAs establishing new animal program management oversight or facility support to ensure they meet regulatory and accreditation requirements
- f. Act on the request of the Institutional Official by conducting unannounced site visits of ACU programs and facilities.
- g. Act on the request of the Institutional Official to implement appropriate corrective actions within the NIH ACU program.
- h. As an agent of the Institutional Official, review and concur with IC requests to create and maintain satellite animal holding facilities.
- i. Review and approve IC-specific proposed additions to the Animal Study Proposal format. (See [IO Policy Memo](#))
- j. Compile the summary report for the NIH annual United States Department of Agriculture (USDA) report of animal use from the collective reports of the IC component animal programs.
- k. Serve as an ex officio (voting) veterinary member of the ARAC.
- l. Compile the AAALAC annual report for the Bethesda-based programs and review and concur with the AAALAC annual reports compiled by other IRP programs.
- m. Compile the AAALAC Overview program description for the Bethesda-based programs and review and concur with the IC program descriptions provided for the IRP programs. Lead and manage the Bethesda-based triennial site visit preparations and execution.
- n. Consult with IC ACUC Chairs and/or APD on issues of potential non-compliance, and when issues are determined to represent serious or continuing non-compliance, report to the IO and OLAW. Track all reported incidents and ensure their timely resolution. Inform AAALAC of all reported events.

**3. The Scientific Director, acting via delegated authority from 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. Appoint, by delegated authority via the IC Director from the IO, an IC ACUC(s). Support to the ACUC(s) shall include, but not be limited to, space, administrative, training, and travel resources.
- c. Ensure participation in the Animal Exposure Program (AEP) (or equivalent, as applicable, for contract personnel), managed by the Occupational Medical Service (OMS), of the Division of Occupational Health and Safety (DOHS), SR, ORS - <https://ors.od.nih.gov/sr/dohs/Documents/AnimalExposureProgram508.pdf>. 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.

#### 4. Principal/Responsible Investigators shall:

- a. Submit a completed Animal Study Proposal, containing at a minimum the information contained on the format shown in [IO Policy Memo](#) to the IC-ACUC Chair for review and approval before requesting animals or initiating animal studies.
- b. Complete the course, "Using Animals in Intramural Research: Guidelines for Principal Investigators," prior to approval and conduct of procedures on an Animal Study Proposal. In addition, every three years, complete the combined refresher training course for Principal Investigators and Animal Users. Both courses can be accessed on the OACU training website: <https://oacu.oir.nih.gov/training-resources>.
- c. Comply with this policy, the Guide, the PHS Policy, and the AWRs.
- d. 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. See the ARAC [Guideline Regarding Changes to Animal Study Proposals](#).
- e. Ensure NIH personnel listed on their Animal Study Proposal(s) meet the training requirements listed under F.5. below to include both mandatory OACU training as well as technical training.
- f. Ensure all personnel listed on their ASP(s) have read and understand all approved ASPs/amendments upon which they are listed as co-investigators or animal users and ensure they have access to copies of all applicable ASPs.
- g. Ensure all personnel listed on an ASP are enrolled in the NIH AEP (or equivalent for contract staff) prior to working with animals.
- h. Seek guidance from the ORS/SR/DOHS Occupational safety and health specialist assigned to the IC when completing the "Hazardous Agent to Humans" section of the ASP.

**5. The Animal User shall:**

- a. Complete the course “Using Animals in Intramural Research: Guidelines for Animal Users” prior to the conduct of procedures in an ASP and, in addition, every three years, complete the combined refresher training course for Principal Investigators and Animal Users. Both courses can be accessed on the OACU training website: <https://oacutrainig.od.nih.gov/>.
- b. Read and understand all approved ASPs/amendments upon which they are listed as co-investigators or animal users,
- c. Be trained for any technical procedures described in ASPs in which they are listed that they are to perform.
- d. Comply with this policy, the Guide, the PHS Policy, and the AWRs.
- e. Enroll in the NIH AEP (or equivalent program for contract staff) prior to working with animals.

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

- a. To their 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.

**7. 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 Scientific Directors of the other ICs and the Director, OACU.**

**8. The Facility Veterinarian:**

- a. Ensures the provision of adequate veterinary care to all animals housed in the facility.
- b. As a member of Facility Management, 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 Scientific Director(s) on matters of space,

personnel and finances as specified in the Intra-agency 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 intra-agency 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.

#### **9. Facility Management:**

- a. Ensures that the day-to-day operation of the animal facility is in compliance with this policy, as well as all applicable regulations, guidelines and policies, and for maintaining accreditable standards of the ACU program and facility.
- b. Ensures that all animal care personnel demonstrate acceptable skill in assigned duties, to include daily observations and reporting findings as appropriate, and in performing techniques with the species of animal for which they are responsible.
- c. Ensures that daily facility operations, such as animal health care, husbandry and provision of supplies and equipment meet programmatic and regulatory requirements.
- d. In Shared Animal Facilities, acts on recommendations from the User Committee and obtains concurrence from the Scientific Director(s) on matters of space, personnel and finances as specified in the Intra-agency Agreement between ICs of the Shared Animal Facility.
- e. 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 Intra-agency agreements with user ICs.
- f. 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.

#### **10. 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 Scientific Director of user ICs and include at least the following:
  - i. Senior intramural scientist from each user IC;
  - ii. 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
  - iii. IC Animal Program Director(s), or their designees, from the user ICs.
  - iv. Representation by each IC, including the Chair, and the number of members from each IC and the disciplines represented, shall be delineated in the Intra-agency Agreement. The veterinarian serving as the Facility Veterinarian shall be a non-voting ex officio member.

- v. A quorum of the Committee shall be defined as a majority of the user ICs represented. On issues where a vote is called, each Committee will determine the mechanism to be used to determine passage (e.g. weighted percentages based on facility occupancy, etc.). The mechanism utilized to determine a passing vote shall be delineated in the Intra-agency Agreement.

**b. Responsibilities -**

- i. Advises Facility Management and the Scientific Director of the Lead IC on matters of space, personnel and finance, or other matters, specified in the Intra-agency Agreement required to support research in the facility and to ensure compliance with this policy, the Guide, the PHS Policy, and the AWRs.
- ii. Submits, in writing, issues on which a minority opinion is filed to the Lead IC Scientific Director. The Scientific Director of the Lead IC, in consultation with the Scientific Directors of the other user ICs and the Director, OACU, will provide written resolution of the issue to the IO within 30 calendar days.

**11. 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 -**

- i. 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, the Animal Research Advisory Committee, and to the Institutional Official.
- ii. The Committee shall be responsible for reviewing operational issues which affect the overall NIH ACU program.
- iii. Recommendations from this Committee shall be presented to the NIH-ARAC and/or the IO as appropriate, for action.

**12. 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 a member of the OACU staff as designated by the OACU Director.

**b. Responsibilities -**

- i. 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.
- ii. The Committee shall be responsible for reviewing facility operational issues which affect the overall NIH ACU program.

**13. 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 Scientific Director, per the authority delegated from the IO. Each IC-ACUC is composed of at least five individuals and includes at least:

- i. 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;
- ii. One practicing scientist experienced in research involving animals;
- iii. One member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy);
- iv. 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
- v. The ombudsman, see paragraph F.14.a.vi, shall serve as an ex-officio member of all ACUCs. The ombudsman is a non-voting member, is not obligated to attend all meetings, and is not counted in determining if a quorum is present.
- vi. A Division of Occupational Health and Safety specialist.

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

- i. Review ACU programs and inspect all IC facilities (including satellite facilities, animal study areas, and areas where any form of surgical manipulations are performed [i.e. minor, major, survival or non-survival]) at least semiannually using the Guide and the AWRs as a basis for evaluation. At least one member of the ACUC (an agent of the ACUC) should visit those remaining IC animal activity areas at least annually. 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. Two members of the

ACUC of each IC housing animals on active studies in Shared or Central Animal Facilities shall review the animals and the animal activities of its investigators in those facilities at least semiannually.

- ii. Prepare written reports of the IC-ACUC semiannual program evaluations conducted as required by the PHS Policy and the AWRs and submit the reports to the IO /OACU in April and October, with a copy to the IC 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 judgment of the IC-ACUC, the Scientific Director, and/or the IO/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 IO. The IO shall report such instances to OLAW. If similar deficiencies are captured in 2 or more consecutive semiannual reports, OACU and the IC-ACUC will consult to resolve the deficiency.

No Committee member wishing to participate in any evaluation may be excluded except for reasons of conflict of interest (e.g. is personally involved in the study). 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.

- iii. 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.
- iv. 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.
- v. 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, PHS Policy and the AWR's. 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.
- vi. Notify the investigators and the institution, i.e., the IC 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, 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. Notices of ASP terminations shall also be provided to Facility management.

- vii. 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. See the ARAC [Guideline Regarding Significant Changes to Animal Study Proposals](#).
- viii. Review, and, if warranted, investigate concerns involving the care and use of animals within the IC research facility and program resulting from complaints received and from reports of noncompliance received from laboratory or research facility personnel, employees, or the public.
- ix. Review all temporary stops of procedures (Section C, Policy) at a convened meeting of a quorum of the IC-ACUC committee to examine cause, and determine any further actions.
- x. Be authorized as designated in PHS policy to suspend all or part of an ASP that it previously approved if it determines that there has been noncompliance with applicable provisions of the AWRs, the Guide, the Institution's Assurance, or the PHS Policy. The IC-ACUC may suspend an ASP 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. When an IC-ACUC considers any suspension of procedures or an ASP, the Investigator(s) must be provided a fair opportunity to present their interpretation and defend against any accusations. When an IC-ACUC suspension occurs it will be reported to the IO through the Director, OACU who will provide an initial preliminary report to OLAW. When the IC-ACUC suspends an ASP, the IC Scientific Director in consultation with the IC-ACUC, shall review the reasons for the suspension, and the appropriate corrective action(s). The IC-ACUC will submit a final report describing the incident and the corrective actions through the Director OACU to the IO. The IO will review the reasons for suspension, and will review and approve or request changes to the corrective action(s) taken, and will make a full report to OLAW.
- xi. Report all instances of noncompliance (protocol, animal facility, and animal program related) to the IO through the OACU Director, in a timely manner, to effect appropriate Institutional communications and to determine if the issue constitutes serious or continuing non-compliance with PHS Policy or a serious deviation from the provisions of the Guide. Issues determined to meet this criteria will be reported by the Director, OACU to the IO and OLAW in an initial preliminary report. After the IC

ACUC investigation has occurred and corrective actions have been approved by the IC ACUC, a comprehensive, final report will be submitted to the IO via the Director, OACU. The IO will review and approve or request changes to the corrective action(s) taken, and will make a full report to OLAW.

- xii. Review all proposed methods of euthanasia and consider waivers for those not recommended in the [American Veterinary Medical Association \(AVMA\) Guidelines 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. Waivers are issued in writing and filed with the ACUC Chair as a part of the Animal Study Proposal.
- xiii. Advise investigators regarding animal care and use as requested by IC investigators, required by the 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.
- xiv. Remain cognizant of animal care and use practices of IC investigators and advise the 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.
- xv. 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 and OACU observers are notified of these meetings in a timely fashion, provides copies of minutes to the Scientific Director, and maintains a file of all minutes, memoranda, waivers, and project review documents. All official documents will be maintained and disposed of in accordance with PHS Policy, the AWRs, and NIH Policy Manual 1743, Managing Federal Records (see Section H., Records Retention and Disposal for details).
- xvi. Prepare the IC's "Annual Report of Research Facility" as required by the USDA, as detailed in the ARAC [Guidelines for Preparing USDA Annual Reports and Assigning USDA Pain & Distress Categories](#), and submit it to the OACU. The OACU will prepare the composite NIH report and submit it to the USDA.
- xvii. Provide oversight of the IC ACU training program and ensuring the program's effectiveness by:
  - 1. Tracking PI and Animal Users completion of mandatory training (See F.4.b & F.5.a. above) and verifying with PIs that the animal users are experienced or have received training on technical, hands-on procedures they will be responsible for conducting.
  - 2. Ensuring new ACUC members complete: "**Animal Care and Use Committee Member Training: Defining the Challenge of ACUC Membership**" provided by OACU. Course registration can be



completed on the OACU training website:

<https://oacutrainng.od.nih.gov/>.

3. Verifying that all animal care staff are experienced or have received training on technical, hands-on procedures they will be responsible for performing.
  4. Identifying training needs for intramural staff who work with laboratory animals, communicate those needs to the Associate Director for Training, OACU, and assist with the development of the appropriate courses.
  5. Advising the SD regarding the requirements for training of professional and technical staff in animal care and use.
- xviii. Advise the Scientific Director concerning newly proposed or enacted legislation, policies, and guidelines regarding laboratory animals, including recommending responses to proposals, and implementing enacted procedures.
- xix. 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 **triennially**. Continuing reviews shall incorporate a program of post-approval monitoring of protocol activities which follows procedures outlined in the ARAC [Guideline for Review and Approval of Animal Study Proposals and Significant Changes](#).

14. **The NIH Animal Research Advisory Committee (NIH-ARAC)** is established by the IO, who appoints its Chair, Executive Secretary, veterinarian, non-scientist, ombudsman, and the non-affiliated member(s). The Executive Secretary and staff support are provided by OACU.

a. **Composition** - The NIH-ARAC includes at least:

- i. 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 are encouraged to attend the meetings.
- ii. 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.
- iii. One practicing scientist experienced in research involving animals.
- iv. One member whose primary concerns are in a non-scientific area.
- v. One individual who is not affiliated with NIH, in any way other than as a member of the NIH-ARAC. This person will provide representation for general community interests in the proper care and treatment of animals.
- vi. 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 ARAC [Guidelines for Responding to Animal Care & Use Complaints from Outside NIH](#).

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

- i. Meets at monthly intervals or as needed to advise the IO 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 IO.
- ii. 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).
- iii. Makes written recommendations to the IO regarding any aspect of the Intramural ACU program, facilities, or personnel training which needs improvement or change.
- iv. Serves in an advisory role to the NIH Director and the IO in all matters involving animal care and research use.
- v. Establishes ARAC Guidelines for use by IC ACUCs in reviewing, interpreting, and providing oversight of animal care and use activities and PIs during conduct of animal procedures.
- vi. Identifies trans-NIH training needs for intramural staff who work with laboratory animals, and assists the Associate Director for Training, OACU with the development of the appropriate courses.
- vii. The Executive Secretary maintains file copies of all meetings: agendas, minutes, membership and authority of the Committee. All official documents are maintained and disposed of in accordance with NIH Policy Manual 1743, Managing Federal Records (see Section H., Records Retention and Disposal for details).

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[1](#) or Executive Secretary, where appropriate  
or Executive Secretary, where appropriate.

## **G. Procedures**

1. **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 guided by the latest ARAC Guidelines on animal transportation:
2. **Transfer of Animals:** The transfer of animals for research purposes, pursuant to section 301 of the Public Health Service Act shall be guided by the [Animal Transfer](#)

[Agreement \(ATA\)](#), or as specified in other binding agreements, such as Material Transfer Agreements Cooperative Research and Development Agreements or other technology-transfer agreements. Note that the ATA serves a separate function from technology-transfer agreements; often both are needed for a given transfer. For further information or for consultation on a specific situation, contact the IC's Technology Development Coordinator.

3. **Controlled Substances:** The acquisition and use of controlled substances for use in research animals shall be in conformance with [NIH Manual 1345](#), Handling and Safeguarding of Controlled Substances for Nonhuman Use.

## H. 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](#), Managing Federal Records, Appendix 4: Records Management Resources, [NIH Records Schedule System](#).

NIH e-mail 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 Liaison or the NIH 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' supervisor, NIH staff conducting official reviews or investigations, and the Office of Inspector General who 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. Back-up files are subject to the same information requests as original messages and documents.

## I. Internal Controls

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

1. **Office Responsible for Reviewing Internal Controls Relative to this Chapter:**  
Office of Animal Care and Use and the Office of Intramural Research.
2. **Frequency of Review (in years):** Ongoing; with formal reports presented to the Animal Research Advisory Committee (ARAC) annually and triennially as described below.
3. **Method of Review:**
  - a. The Scientific Directors participate in the Annual 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.

- b. The Intramural Program must provide annual reports to both the United States Department of Agriculture and the NIH Office of Laboratory Animal Welfare (OLAW.) These agencies have regulatory authorities over the NIH IRP ACU program. Additionally, per the PHS Policy, instances of serious or continuing non-compliance are required to be reported to OLAW.
- c. The Intramural Program must provide annual reports to AAALAC and triennially AAALAC performs site visits to all accredited IRP ACU programs.

4. **Review Reports are sent to:** the Deputy Director for Intramural Research to indicate that controls are in place, working well, and to identify any issues of concern.

## Appendix 1- References

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

### 1. Laws:

- [Animal Welfare Act](#) (7 U.S.C. 2131 et. seq.)
- [The Endangered Species Act of 1973](#) (16 U.S.C. 1531 et. seq.)
- The Public Health Services (PHS) Act, as amended ([Organization of National Institutes of Health: 42 U.S.C. §281](#), [Plan for use of animals in research: §283e](#), [Animals in Research: §289d](#))
- [Health Research Extension Act of 1985](#) (Pub. L. No. 99-158)

### 2. Regulations:

- [Animal Welfare, 9 CFR](#), Chapter 1, Subchapter A, Parts 1, 2, 3, and 4
- [Good Laboratory Practice for Nonclinical Laboratory Studies](#) (Title 21, CFR, Part 58)
- Acquisitions Involving the Use of Laboratory Animals ([48 CFR 370.4](#))
- [PHS Policy on Humane Care and Use of Laboratory Animals](#), Revised 2015

### 3. Standards: (Current versions)

- [U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#)
- [Guide for the Care and Use of Laboratory Animals](#), National Research Council
- [NIH Animal Research Advisory Committee Guidelines](#)
- [AVMA Guidelines for the Euthanasia of Animals](#)
- [Biosafety in Microbiological and Biomedical Laboratories](#), HHS/CDC
- [Adequate Veterinary Care](#), Report of the American College of Laboratory Animal Medicine

### 4. NIH Policy Manuals and other Animal Program Policies:

- [NIH Manual 1165](#), Agency Agreements
- [NIH Manual 1345](#), Handling and Safeguarding of Controlled Substances for Nonhuman Use
- [NIH Manual 1743](#), Managing Federal Records
- [NIH Manual 3040-3](#), Intramural Acquisitions Involving Animal Research Activities
- [IRP Animal Program Policy Manuals](#)
- [DOHS Animal Program Policies](#)
- [NIH Delegations of Authority, Program: General, No. 31, Intramural Animal Care and Use Program](#)