

# 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 policy established responsibility for the humane care and use of animals within the Intramural Research Program (IRP) of the National Institutes of Health (NIH). This revised chapter establishes responsibility for the humane care and use of animals within the intramural research program of NIH. This revision includes updates to the policy and responsibilities sections, as well as, revised definitions (Appendix 2), and new references (Appendix 1).
- 2. Filing Instructions:**

- **Remove:** NIH Manual Chapter 3040-2, dated 04/22/2014
- **Insert:** NIH Manual Chapter 3040-2, dated 04/13/2023

**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 the humane care and use of animals within the Intramural Research Program (IRP) of the National Institutes of Health (NIH). 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 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. The use of animal models is a critical component of this research.

## B. Scope

This policy applies to NIH personnel including federal employees, contractors, trainees, students, volunteers, and guest researchers who are involved in the oversight, maintenance, research, or care of animals in the NIH IRP. This policy is applicable to all NIH-conducted or supported intramural activities involving animals – except at the National Cancer Institute in Frederick, Maryland.

## C. Policy

To maintain the highest level of responsible animal care and use, everyone involved in the care or use of animals within the NIH IRP must adhere to the applicable humane and ethical policies as established or referenced herein. Animals will be maintained in accordance with the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the *Guide for the Care and Use of Laboratory Animals (Guide)*, the Animal Welfare Act and Regulations (AWARs), and the provisions of the NIH IRP Animal Welfare Assurance (Institutional Assurance). Appendix 1 contains a comprehensive list of these laws, regulations, standards, NIH policy manual chapters (MC), and animal program policies. The NIH, as an institution, will maintain full accreditation with AAALAC International.

## D. Responsibilities

1. The **Deputy Director for Intramural Research (DDIR)**, NIH, through delegated authority from the NIH Director serves as the Institutional Official (IO). The DDIR is responsible for the oversight of the NIH IRP animal program and for ensuring compliance with this policy.
2. The **Director of the Office of Animal Care and Use (OACU)** has the authority delegated by the IO for day-to-day oversight and implementation of the IRP animal care and use program. The OACU Director will:
  - a. Monitor and ensure compliance with the Institutional Assurance. This includes preparation of Assurance documents, correspondence, and reports to the Office of Laboratory Animal Welfare (OLAW).
  - b. Ensure adequate veterinary care meets the standards set forth in American College of Laboratory Animal Medicine Position Statement on Adequate Veterinary Care (See Appendix 1).
  - c. Review semiannual program review and inspection reports for compliance with the Institutional Assurance, and forward copies of the Institute, Center, or Office (ICO) semiannual evaluations with a trend analysis to the IO.
  - d. Determine whether deficiencies reported in the semiannual program review and inspection reports are significant or minor in consultation with the ICO Animal Care and Use Committee (ACUC) and the IO.

- e. Designate OACU staff members to serve as non-voting observers on the ICO ACUCs.
- f. Review animal facility construction plans to verify compliance with animal welfare regulations.
- g. Review Intra-agency Agreements (IAAs) establishing new animal program management oversight or facility support prior to their implementation, to ensure compliance with regulatory and program accreditation requirements.
- h. Advise the IO and the Animal Research Advisory Committee (ARAC) concerning newly proposed or enacted legislation, policies, and guidelines regarding laboratory animals.
- i. Conduct site visits of ICO Animal Care and Use Programs (ACUP) and facilities to verify compliance with applicable laws, standards, and guidelines as listed in Appendix 1.
- j. Assist in the coordination of corrective actions for deficiencies identified in the NIH ACUP.
- k. Review ICO requests to create and maintain satellite animal holding facilities.
- l. Serve as an ex officio (voting) veterinary member of ARAC.
- m. Consult with ICO ACUC Chairpersons and/or Animal Program Directors (APDs) on issues of potential noncompliance.
- n. Have the authority to temporarily halt or stop a protocol or procedure involving animals if it is determined the activity is not being conducted in accordance with the approved ASP, pending prompt review by the ICO ACUC.
- o. Consult with ACUCs regarding suspensions of animal activities and subsequent corrective actions.
- p. Report to the IO, OLAW, and AAALAC International, serious animal incidents or regulatory noncompliance issues, and track all reported incidents and ensure their timely resolution.
- q. Lead and manage the general Bethesda-based AAALAC International triennial accreditation site visit.
- r. Review ICO animal program descriptions provided to AAALAC International prior to their triennial site visit.
- s. Oversee other general animal program site visits.
- t. Compile the AAALAC International annual report for the Bethesda-based programs and review the annual reports compiled by other IRP programs.
- u. Compile the United States Department of Agriculture (USDA) Annual Report of Research Facility for the IRP ACUP.
- v. Maintain records of accrediting body determinations.
- w. Review, on behalf of the DDIR/IO, ICO written requests for waivers to the provisions of this manual chapter. The DDIR/IO may grant waivers to those providing sufficient justification.

3. **ICO Scientific Directors (SD)** have authority delegated by the DDIR for ensuring compliance with this policy at the ICO level. The SDs will:

- a. Consider initiating appropriate action regarding recommendations from the IO, ICO APD, or ICO ACUC.

- b. Appoint members to the ICO ACUC.
- c. Provide support to the ICO ACUC(s) including, but not limited to space, administrative, training, and travel resources.
- d. Ensure ICO animal users participate in the Animal Exposure Program (AEP) or an equivalent program for contract personnel.
- e. Ensure the review of Animal Study Proposals (ASPs) based on scientific merit and sex as a biological variable.
- f. Establish a Nonhuman Primate (NHP)-specific Scientific Merit Review (SMR) committee and appoint its members when required by the DDIR/IO SMR policy memorandum.
- g. Have the authority to temporarily halt or stop an ASP or a procedure involving animals if it is determined the activity is not being conducted in accordance with the approved ASP, pending prompt review by the ICO ACUC.
- h. Review and approve Central Animal Facility (CAF) and Shared Animal Facility (SAF) IAAs and Standard Operating Procedures (SOP) pertinent to the operation of these facilities to include matters of space, personnel, and finances as specified in the IAA between the ICOs of the SAF.
- i. Review and approve the ICO's feeder report to the NIH USDA Annual Report of Research Facility.
- j. Review the ICO ACUC's semiannual facility inspection and program review reports.

**4. Principal Investigators (PI) will:**

- a. Ensure compliance with this policy by lab staff and animal users listed on their approved ASPs.
- b. Complete the course, "Using Animals in Intramural Research: Guidelines for Principal Investigators," before conduct of procedures on an ASP. In addition, complete the combined refresher training course for "Principal Investigators and Animal Users" triennially.
- c. Submit a completed ASP to the ICO ACUC for review and approval before requesting animals or initiating animal study activities.
- d. Consult with the ICO APD or other ICO Veterinarian for ASPs and amendments involving anesthesia, analgesia, tranquilization, or euthanasia.
- e. Consult with the Department of Occupational Health and Safety (DOHS) Safety Specialist (or DOHS designee) assigned to the ICO for ASPs and amendments involving hazardous agents.
- f. Submit any proposed changes to an ASP to the ACUC for review and approval before initiation of the change. This includes refinements and additions to animal activities developed during the conduct of procedures as outlined in the ARAC Guideline, Changes to Animal Study Proposals (Appendix 1).
- g. Report any proposed PI changes or ASP closures to the ICO ACUC immediately.
- h. Ensure animal users listed on an ASP complete NIH required animal use, safety, and technical training.
- i. Ensure all animal users listed on an ASP are enrolled in the NIH AEP (or an equivalent program for contract personnel) prior to working with animals and

- comply with annual medical surveillance requirements as applicable.
- j. Ensure any animal user listed on an ASP who sustains an injury, illness, or potential allergic reaction related to animal exposure reports to Occupational Medical Services (OMS) for evaluation.
  - k. Ensure the animal users listed on an ASP have read, understand, and have immediate access to the active ASP and amendments.
  - l. Communicate animal welfare concerns as outlined in the DDIR/IO policy memo, “Communicating Animal Care and Use Concerns within the NIH Intramural Research Program.”

**5. Responsible Investigators (RI) will:**

- a. Accept responsibility for the PI’s conduct of an ASP when the PI is a Trainee, Adjunct Investigator, Special Volunteer, or Contract Employee.
- b. Sign the ASP as the RI, in addition to the PI and the Lab/Branch Chief.
- c. Complete the course, “Using Animals in Intramural Research: Guidelines for Principal Investigators,” before conduct of procedures on an ASP. In addition, complete the combined refresher training course for “Principal Investigators and Animal Users” triennially.
- d. Provide input to the project officer and/or contracting officer for issues related to animal care and use when the contract employee is the PI.
- e. Provide input to the PI’s mentor or supervisor for issues related to animal care and use if the RI is not the PI’s mentor or supervisor.
- f. Potentially serve as the mentor or supervisor of the PI when the PI is a Postdoctoral Fellow or Adjunct Investigator.

**6. Animal Users will:**

- a. Comply with this policy.
- b. Complete the course “Using Animals in Intramural Research: Guidelines for Animal Users” before conducting animal work and complete the combined refresher training course for “Principal Investigators and Animal Users” triennially.
- c. Receive ICO required safety, technical, and surgical training for any animal-related procedures they will perform before starting those procedures.
- d. Enroll in the NIH AEP (or an equivalent program for contract personnel) prior to working with animals and comply with annual medical surveillance requirements as applicable.
- e. Report to OMS for evaluation of any injury, illness, or potential allergic reaction related to animal exposure, and report the incident to PI.
- f. Ensure inclusion on an approved ASP before starting ASP-related animal work.
- g. Read, understand, and ensure access to all approved ASPs and amendments before starting work.
- h. Report animal welfare concerns as outlined in the DDIR/IO policy memo, “Communicating Animal Care and Use Concerns within the NIH Intramural Research Program.”

**7. Animal Program Directors (APD) will:**

- a. Ensure ICO compliance with this policy.
- b. Have delegated authority from their ICO SD for the day-to-day implementation of their ICO animal program.
- c. Oversee the ICO animal care and use program and be provided with the necessary authority, access, and resources to manage the program.
- d. Assume responsibility for the provision and documentation of adequate veterinary care, including animal husbandry, animal health, animal transportation, and study coordination.
- e. Ensure all animal care personnel are qualified to perform their duties.
- f. Serve as a voting member of the ICO ACUC or designate another veterinarian to fulfill this role.
- g. Serve as the Attending Veterinarian or designate another veterinarian to fulfill this role.
- h. Have the authority to temporarily halt or stop a protocol or procedure involving animals if it is determined the activity is not being conducted in accordance with the approved ASP, pending prompt review by the ICO ACUC.
- i. Ensure the review and documentation of veterinary-related exercise exemptions for dogs at least every 30 days unless the exemption is based on a permanent condition.
- j. Ensure the review and documentation of veterinary-related social housing exemptions for nonhuman primates at least every 30 days unless the exemption is based on a permanent condition.

**8. APDs of a Lead ICO for a Shared or Central Animal Facility will:**

- a. Ensure ICO compliance with this policy.
- b. Receive delegated authority from the Lead ICO SD to ensure compliance with the IAA.
- c. Have the authority to temporarily halt or stop a protocol or procedure involving animals if it is determined the activity is not being conducted in accordance with the approved ASP, pending prompt review by the ICO ACUC that approved the activity.

**9. Facility Veterinarians (or equivalent) will:**

- a. Ensure animal facility operations, including animal health care, husbandry, and provision of supplies and equipment are in compliance with this policy and programmatic and regulatory requirements outlined in the approved guidelines and policies.
- b. Ensure the provision of adequate veterinary care to all animals housed in the facility.
- c. Ensure all animal care personnel are qualified to perform their duties.
- d. In a SAF, act on recommendations from the User Committee and obtain concurrence from the SD(s) on matters of space, personnel, and finances as

specified in the IAA between ICOs of the SAF.

- e. In a CAF, act on directions from the Director, Office of Research Services (ORS) on matters of space, personnel, and finances as specified by SOPs or specifically in IAAs with user ICOs.
- f. Work with the PIs and the APD to ensure refinements and/or additions to animal activities developed with investigative staff are communicated to the ICO's ACUC in a timely fashion.
- g. Have the authority to temporarily halt or stop a protocol or procedure involving animals if it is determined the activity is not being conducted in accordance with the approved ASP, pending prompt review by the ICO ACUC.

**10. Facility Management will:**

- a. Ensure animal facility operations, including animal health care, husbandry, signage, and provision of supplies and equipment are in compliance with this policy.
- b. Maintain AAALAC-accreditable standards of the ICO ACUC and facility.
- c. Ensure all animal care personnel are qualified to perform their duties.
- d. Work with the PIs and the APD to ensure refinements and/or additions to animal activities developed with investigative staff are communicated to the ICO ACUC in a timely fashion.
- e. In a SAF, act on recommendations from the User Committee and obtain concurrence from the SD(s) on matters of space, personnel, and finances as specified in the IAA between ICOs of the SAF.
- f. In a CAF, act on directions from the Director, ORS on matters of space personnel and finances as specified by the SOPs or specifically in IAAs with user ICOs.

**11. Each ICO using animals will maintain an **ICO ACUC** appointed by the SD, per delegated authority from the IO. The **ACUC** will:**

- a. Review, at least once every six months, the ICO's program for humane care and use of laboratory animals, using the *Guide* as a basis for evaluation.
- b. Inspect, at least once every six months, all the ICO's animal facilities (including satellite facility and study areas, as applicable) using the *Guide* as a basis for evaluation (see Appendix 1 – ARAC Guidelines for ACUC Oversight of Satellite Facilities, Study Areas, Laboratories, and other Animal Activity Areas and ARAC Guidelines for ACUC Oversight of Animal Study Proposal Activities in Shared and Central Facilities).
  - i. For USDA-regulated species, at least two ACUC members are required to assist in conducting the inspection.
  - ii. For non-USDA-regulated species, at least one qualified individual is required to conduct the inspection.
- c. Prepare reports of the evaluations conducted and submit the reports to the IO through OACU with a copy to the ICO SD (see Appendix 1 – ARAC Guidelines on Classifying Deficiencies Identified During Semiannual Evaluations).

- d. Review and, if warranted, investigate concerns involving the care and use of animals at the ICO.
- e. Make recommendations to the SD and/or IO regarding any aspect of the ICO's animal program, facilities, or personnel training.
- f. Review and approve, require modifications in (to secure approval), or withhold approval of animal activities (see Appendix 1 – ARAC Guidelines for Review and Approval of Animal Study Proposals and Significant Changes).
- g. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities (see Appendix 1 – ARAC Guidelines Regarding Changes to Animal Study Proposals).
- h. Be authorized to suspend an activity involving animals and review all temporary stops of procedures to determine cause and any further actions. Any suspension of animal activities must also be reported to the IO through OACU.
- i. Prepare reports to the IO through OACU, describing circumstances and corrective actions taken regarding any serious noncompliance with PHS Policy, AwarDs, and the *Guide*.
- j. Conduct continuing reviews of previously approved, ongoing animal activities at appropriate intervals as determined by the ACUC, including a complete review at least once every three years.
  - i. Review scientific exercise exemptions for dogs at least annually.
  - ii. Review scientific exemptions for social housing of nonhuman primates at least annually (see Appendix 1 – ARAC Guidelines for Social Housing of Social Species).
- k. Provide oversight of the ICO ACU training program and ensure the program's effectiveness by tracking completion of mandatory training and completion of position-specific training on technical/hands-on procedures.
- l. Ensure all ACUC members complete the course, "Animal Care and Use Committee Member Training: Defining the Challenge of ACUC Membership."
- m. Meet semiannually or more often as needed.
- n. Maintain the following records: minutes of ACUC meetings (including records of attendance, activities of the committee, and committee deliberations); records of animal study proposals and proposed significant changes indicating whether ACUC approval was given or withheld; records of semiannual ACUC reports and recommendations (including minority views).
- o. Conform to the following membership requirements (see Appendix 1 – ARAC Guidelines for Animal Care and Use Committee Membership):
  - i. There must be at least five members on the committee, one of whom serves as the Chairperson.
  - ii. There may be no more than three members from the same administrative unit of the institute.
  - iii. There must be at least one veterinarian with direct or delegated animal program responsibility.



- iv. There must be at least one nonaffiliated member. Nonaffiliated members must represent the general community interests in the proper care and use of animals. The nonaffiliated member cannot be a former or current laboratory animal user, affiliated with the institution, or an immediate family member of an individual affiliated with the institution.
- v. There must be at least one practicing scientist experienced in research involving animals.
- vi. There must be at least one member whose primary concerns are in a nonscientific area. Nonscientific members must not have scientific training.
- vii. There must be at least one DOHS Safety Specialist member (or DOHS designee).
- viii. The ARAC ombudsman will serve as ex-officio, non-voting member, is not obligated to attend all meetings, and is not counted in determining if a quorum is present.

12. The **DOHS Director** is the senior occupational health and safety authority for the NIH who directs the NIH Occupational Health and Safety Program (OHSP) in accordance with federal, state, and local regulations. The Director will ensure the OHSP includes programs supporting the ACUP as outlined in the *Guide*, and will include at a minimum:

- a. risk control and prevention strategies,
- b. hazard identification and risk assessment,
- c. facility design and construction,
- d. safety equipment selection and exposure monitoring,
- e. personnel training,
- f. personal hygiene,
- g. personal protective equipment, and
- h. medical evaluation and preventive medicine for personnel.

13. The following advisory committees will assist with the administration of the NIH/IRP ACUP by providing technical advice and recommending policies regarding animal care and use.

- a. **User Committee for Shared Animal Facilities**, appointed by the SD(s) of SAF user ICOs, will:
  - i. Advise Facility Management and the Lead ICO SD for each SAF on matters of space, personnel and finance, or other matters specified in the IAA required to support research in the facility and to ensure compliance with this policy.
  - ii. Define within an IAA the number of members from each ICO, the disciplines represented, and the mechanism to be used to determine passage (e.g., weighted percentages based on facility occupancy, etc.) for issues requiring a vote.

- iii. Meet at least annually.
- iv. Ensure a quorum, defined as a majority of the user ICOs represented, to conduct official business.
- v. Delineate within an IAA the user committee membership requirements that will include:
  - A Chairperson
  - A senior intramural scientist from each user ICO
  - Administrative personnel from each user ICO designated to represent the ICO on matters of finance, personnel, space, and other issues which may arise
  - ICO APDs, or their designees, from the user ICOs
  - A facility veterinarian will serve as an ex officio, non-voting member

**b. Animal Program Director Committee will:**

- i. Review operational issues which affect the NIH IRP ACU program and provide advice and recommendations to the OACU Director, ARAC Chairperson, and the IO.
- ii. Meet monthly, or as needed.
- iii. Be composed of the APDs of each ICO. The Chairperson will be elected from the membership. Administrative support will be provided by OACU.

**c. Animal Program Advisory Committee will:**

- i. Review facility and operational issues which affect the NIH IRP ACU program and provide advice and recommendations to the APD Committee Chairperson and the OACU Director.
- ii. Meet at least quarterly.
- iii. Consist of Facility Veterinarians and Facility Managers from the ICOs, members from ORS, and other NIH central service providers. The Chairperson will be elected from the membership. Administrative support will be provided by OACU.

**d. Animal Research Advisory Committee** is established by the DDIR/IO, who appoints the Chairperson, Executive Secretary, veterinarian, nonscientist, ombudsman, and nonaffiliated members. The **ARAC** will:

- i. Serve in an advisory role to the NIH Director and the IO in all matters involving animal care and research use.
- ii. Advise the IO on the Institution's program for humane care and use of animals and support the Institution's conformance to this policy.
- iii. Review ICO and/or trans-NIH concerns involving the care and use of animals at NIH following investigation, deliberation, and closure by the

ICO ACUC.

- iv. Make written recommendations to the IO regarding any aspect of the Intramural ACU program, facilities, or personnel training which needs improvement or change.
- v. Establish ARAC Guidelines for use by ICOs in reviewing, interpreting, and providing oversight of animal care and use activities and PIs during conduct of animal procedures.
- vi. Identify trans-NIH training needs for intramural staff who work with laboratory animals and assist OACU with the development of the appropriate courses.
- vii. Meet monthly, or as needed.
- viii. Consist of at least:
  - The ARAC Chairperson.
  - The Chairperson from each ICO ACUC. The Vice Chairperson will serve as the alternate member from each IC. APDs will not serve as the alternate member from each ICO but are encouraged to attend the meetings.
  - One Doctor of Veterinary Medicine with training or experience in laboratory animal science and medicine who has delegated or direct oversight responsibility for compliance of activities involving animals at NIH.
  - One practicing scientist experienced in research involving animals.
  - One member whose primary concerns are in a non-scientific area.
  - One individual who is not affiliated with NIH, in any way other than as a member of the ARAC. This person will provide representation for general community interests in the proper care and treatment of animals.
  - One member who is responsible for the NIH OHSP.
  - An ombudsman 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.
- ix. Receive Executive Secretary and administrative support from OACU. The Executive Secretary maintains file copies of all meeting agendas, minutes, membership, and authority of the Committee. The Executive Secretary also ensures all members are notified of the meetings and provides copies of the minutes to the IO.

## Appendix 1: References

### 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 (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](#))
4. [Health Research Extension Act of 1985](#) (Pub. L. No. 99-158)

### B.Regulations

1. Animal Welfare Act Regulations, 9 CFR:
  - a. [Subchapter A – Part 1 – Animal Welfare](#)
  - b. [Subchapter A - Part 2 – Regulations](#)
  - c. [Subchapter A - Part 3 – Standards](#)
  - d. [Subchapter A - Part 4 – Rules of Practice Covering Proceedings Under the Animal Welfare Act](#)
2. [Good Laboratory Practice for Nonclinical Laboratory Studies](#) (Title 21, CFR, Part 58)
3. [Acquisitions Involving the Use of Laboratory Animals](#) (48 CFR 370.4)

### C.Standards and Policies

1. [U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#)
2. [PHS Policy on Humane Care and Use of Laboratory Animals](#)
3. *Guide for the Care and Use of Laboratory Animals*, National Research Council
4. [AVMA Guidelines for the Euthanasia of Animals](#)
5. [Biosafety in Microbiological and Biomedical Laboratories](#), HHS/CDC
6. [Adequate Veterinary Care](#), Report of the American College of Laboratory Animal Medicine
7. [AAALAC International Accreditation Program Standards](#)
8. [Design Requirements Manual](#), NIH

### D.NIH Animal Program and Related Policies

1. [NIH Manual Chapter 1165](#), Agency Agreements
2. [NIH Manual Chapter 1340](#), NIH Occupational Safety and Health Management Program
3. [NIH Manual Chapter 1341](#), Working with Radioactive Materials or Radiation Producing Machinery

4. [NIH Manual Chapter 1345](#), Handling and Safeguarding of Controlled Substances for Nonhuman Use
5. [NIH Manual Chapter 1743](#), Managing Federal Records
6. [NIH Manual Chapter 3015](#), Admittance of Minors to Hazardous Areas
7. [NIH Manual Chapter 3032](#), Environmental Management and Waste Minimization at the NIH
8. [NIH Manual Chapter 3034](#), Working with Hazardous Chemicals
9. [NIH Manual Chapter 3035](#), Working Safely with Potentially Hazardous Biological Materials
10. [NIH Manual Chapter 3036](#), NIH Laser Safety Program
11. [NIH Manual Chapter 3037](#), NIH Biological Surety Program
12. [NIH Manual Chapter 3040-3](#), Intramural Acquisitions Involving Animal Research Activities
13. [NIH Manual Chapter 3043-1](#), Introduction of Rodents, and Rodent Products and Rodent Pathogens from Non-Approved Sources
14. [NIH Manual Chapter 3044-1](#), Nonhuman Primate Quarantine
15. [NIH Manual Chapter 3044-2](#), Protection of NIH Personnel Who Work with Nonhuman Primates
16. [NIH Manual Chapter 3047](#), Trans-NIH Animal Facility Security Program
17. [NIH ARAC Guidelines](#)
18. [NIH DDIR/IO Policy Memos](#)
19. [DOHS Animal Program Policies](#)
20. [NIH Delegations of Authority, Program: General, No. 31, Intramural Animal Care and Use Program](#)

## Appendix 2: Definitions

1. **Full Accreditation** – The recognition by AAALAC International that the animal facilities and management practices of an organization meet or exceed AAALAC International standards.
2. **Animal** – Any live vertebrate animal used or intended for use in research, experimentation, testing, training, or related purposes. This definition extends to animals that are acquired for the purpose of collecting tissues.
3. **Animal Exposure Program (AEP)** – An occupational health program managed by the Occupational Medical Service (OMS), DOHS that provides relevant health and safety information related to the care and use of animals, occupationally indicated immunizations, and clinical evaluation and treatment for individuals with animal related injuries and illnesses. This program applies to participants in the Biological Surety Program and federal employees who have direct contact or are involved in the direct care of live animals, that share “air space” with a nonhuman primate (NHP), or those that work with non-fixed Old World NHP tissue or body fluids. Individuals electing not to participate in the AEP may be denied permission to participate in animal studies. Contract employees are required to be enrolled in a contractor-provided program equivalent to the AEP.

4. **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.
- **Central Animal Facility (CAF):** An animal facility managed by the Office of Research Services (ORS), Division of Veterinary Resources (DVR) and utilized by more than one Institute, Center or Office (ICO).
  - **Satellite Facility (SF):** Any building, room, area, enclosure, or other containment outside of a core animal facility or centrally designated or managed area in which animals are housed for more than 24 hours.
  - **Shared Animal Facility (SAF):** An animal facility shared by more than one ICO and managed by a Lead ICO.
  - **Study Area (SA):** Any building, room, area, enclosure, or other containment outside of a core facility or centrally designated or managed area in which USDA-regulated animal species are housed for more than 12 hours.
5. **Animal Study Proposal (ASP)** – The document describing any research activity involving vertebrate animals completed by a PI and submitted to the ICO ACUC for review and approval prior to the acquisition of animals or initiation of the study.
6. **Animal Welfare Act (AWA)** – The U.S. Federal law regulating the treatment of animals in research, teaching, testing, and exhibition.
7. **Animal Welfare Act Regulations (AWARs)** – The regulations associated with the AWA which interpret the law into enforceable standards contained in 9 CFR, Parts 1, 2, and 3.
8. **Animal User** – An individual who may conduct animal procedures described in an ASP.
9. **Facility Management** – Individual(s) operating under the direction of the APD, responsible for the day-to-day management of NIH animal facilities.
10. **The Guide for the Care and Use of Laboratory Animals (Guide)** – an internationally accepted primary reference on animal care and use.
11. **Institute, Center, or Office (ICO)** - The NIH organizational component responsible for a particular grant program or set of activities. Each ICO has its own research agenda, driven by its focus on specific diseases, conditions, body systems, public health needs, scientific opportunities, or other strategic goals.
12. **Institution** - The NIH Intramural Research Program (IRP).
13. **Institutional Assurance** - The documentation from an institution assuring compliance with the PHS Policy on Humane Care and Use of Laboratory Animals and the *Guide*.
14. **Institutional Official (IO)** - The individual who bears ultimate responsibility for the program and has authority to allocate resources needed to ensure the program's overall effectiveness. The NIH Deputy Director for Intramural Research (DDIR) serves as the IO.
15. **Intra-agency Agreement (IAA)** - A written arrangement between/among NIH components, all of which must have the statutory authority to engage in the arrangement.

16. **Lead Institute, Center, or Office (Lead ICO)** - The ICO authorized through an IAA to manage a SAF/CAF. In addition to the requirements in MC 1165, IAAs for SAFs will include the management plan/standard operating procedures of the facility, and the composition, structure, and function of the User Committee.
17. **Office of Animal Care and Use (OACU)** - The office ensuring NIH animal programs and facilities are in compliance with this policy, the *Guide*, the PHS Policy, and the AWRs, and maintain Full Accreditation with AAALAC International.
18. **PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy)** - The set of standards administered by the Office of Laboratory Animal Welfare (OLAW) requiring institutions establish and maintain proper measures to ensure the appropriate care and use of all vertebrate animals involved in research, research training, and biological testing activities conducted or supported by the U.S. Federal Government.
19. **U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training (U.S. Government Principles)** - The set of principles developed by the Interagency Research Animal Committee (IRAC) for government agencies to use in developing requirements for testing, research, or training procedures involving the use of vertebrate animals.
20. **Principal Investigator (PI)** - An individual with the overall responsibility for the design, conduct, and reporting of research involving animals.
21. **Refinement** - Those actions which alleviate or minimize the pain, distress or other adverse effects experienced by the animals involved, and/or enhance animal well-being.
22. **Responsible Investigator (RI)** – A scientist who is an NIH federal employee with knowledge and authority to oversee ASP activities conducted by or on behalf of a PI who is not an NIH federal employee (e.g., contract employee, special volunteer, adjunct investigator, trainee, etc.).
23. **USDA-Regulated Species** - All live, warm-blooded species acquired or bred specifically by/for the NIH for use in the IRP except for aquatic species; birds; rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research.
24. **Veterinarian** – An individual who possesses a doctorate in veterinary medicine or equivalent degree that meets additional requirements set forth by the employing IC.
  - **Animal Program Director (APD):** A Veterinarian with direct or delegated authority for the day-to-day implementation of an IC animal program.
  - **Attending Veterinarian (AV):** The IC APD or other veterinarian as designated by the IC APD responsible for the health and wellbeing of all laboratory animals used at the IC.
  - **Facility Veterinarian (or equivalent):** A Veterinarian responsible for the health and wellbeing of animals at a specific facility.