

NIH POLICY MANUAL

3040-3 INTRAMURAL ACQUISITIONS INVOLVING ANIMAL RESEARCH ACTIVITIES

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1. **Explanation of Material Transmitted:** This revised chapter establishes responsibility for monitoring the humane care and use of animals involved in research, research training, and biologic testing activities which are conducted under contract including simplified acquisition mechanisms.

2. **Filing Instructions:**

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INTRAMURAL ACQUISITIONS INVOLVING ANIMAL RESEARCH ACTIVITIES

A. Purpose: This chapter establishes responsibility for monitoring humane care and use of animals involved in research, research training, and biologic testing activities which are conducted under contract, including simplified acquisition mechanisms, by elements of the NIH intramural research program.

B. Background:

This policy establishes the requirements for institutional oversight of contracts, including simplified acquisitions, which involve animals by elements of the intramural NIH research program. The authority for this policy is granted by the PHS Policy on Humane Care and Use of Laboratory Animals and the federal Animal Welfare Act regulations.

Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) rules of accreditation state that when animals used at a contract site are owned by the parent institution, in this case NIH, either the contractor must have an AAALAC accredited program, or the contract facility and its animal care and use program become an integral part of NIH's program and will be visited and subject to NIH site-visit proceedings.

Institutions receiving PHS funds for activities involving animals must either have their own Assurance on file and approved by the Office of Laboratory Animal Welfare (OLAW) or be included in the NIH Assurance. Under unusual circumstances, when it is necessary for an NIH contractor to be included in the NIH Assurance, the Institute or Center must assume responsibility for compliance of the contractor's animal care and use program with provisions of PHS Policy. OLAW's position on the role of the Institutional Animal Care and Use Committee (IACUC) in the oversight of animal activities at a contract site states: "When both the PHS Grantee and its Contractor hold OLAW-approved Assurances, some latitude is allowed in determining which IACUC (if not both) will review the proposal. However, the institution which subcontracts any animal activity retains partial accountability for providing effective oversight mechanisms to ensure compliance with the PHS Policy."

C. References:

1. HHS Acquisition Regulations 352.270-9 Care of Laboratory Animals, 48 CFR Section 353.27-9 or as amended (HHSAR) available on the Web at <http://knownet.hhs.gov/acquisition/hhsar/#352.270-9%20Care%20of%20laboratory%20animals>
2. PHS Policy on Humane Care and Use of Laboratory Animals, Revised 2002 (PHS Policy) available on the Web at <http://grants.nih.gov/grants/olaw/references/phspol.htm> .
3. NIH Manual Chapter 3040-2, Animal Care and Use in the Intramural Program available on the Web at <http://www1.od.nih.gov/oma/manualchapters/intramural/3040-2/> .
4. Guide for the Care and Use of Laboratory Animals, Institute for Laboratory Animal

Research, Commission on Life Sciences, NRC, National Academy Press, 1996 (Guide) available on the Web at <http://www.nap.edu/readingroom/books/labrats/>.

D. Definitions:

1. **Accreditation** - The recognition by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) or other Public Health Service (PHS)-recognized accrediting body that the animal facilities and management practices of a research institution are in accordance with the Guide.
2. **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, antibodies or other parts or products. (The acquisition and transportation of certain invertebrates and parts of certain vertebrates are also subject to Federal regulation.)
3. **Animal Activity** - Any research, research training or biological testing activity that involves the use of animals.
4. **Animal Research Advisory Committee (ARAC)** - The intramural NIH Animal Research Advisory Committee includes the Chair of each IC Animal Care and Use Committee (ACUC). The Deputy Director for Intramural Research shall appoint the Chair, Executive Secretary and additional members in concert with the PHS Policy and the Animal Welfare Regulations (AWRs).
5. **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.
6. **Assurance** - The Animal Welfare Assurance filed with the NIH Office of Laboratory Animal Welfare (OLAW) certifying that the institution's research program is in compliance with the PHS Policy.
7. **Authorized Purchasing Agent** - An individual who has been issued a warrant (a Certificate of Appointment) by the Head of the Contracting Activity authorizing him/her to obligate the Government (within specified dollar limits) for commodities and services.
8. **Contract** - A contract is a mutually binding legal relationship obligating the vendor to furnish the supplies or services and the buyer to pay for them. It generally includes commitments that obligate the NIH component to an expenditure of appropriated funds and that, except as otherwise authorized, are in writing. **(Examples include: orders for in vivo production of custom antibodies procured using a government-wide commercial purchase card; or purchase orders for services to maintain research animals at**

contractor facilities.)

9. **Contracting Officer** - An individual who has been issued a warrant (a Certificate of Appointment) by the Head of the Contracting Activity authorizing him/her to enter into, administer, and terminate contracts and to make related determinations and findings. The warrant authorizes the individual (within specified dollar limits) to obligate the Government for commodities and services. A contracting officer may be an administrative officer or other authorized purchasing agent.
10. **Institute/Center-Animal Care and Use Committee (IC-ACUC)** - A committee appointed (via delegated authority from the Director, NIH through the Deputy Director for Intramural Research, see NIH Manual 1130, Delegations of Authority, Program: General # 31 at: <http://www3.od.nih.gov/oma/manualchapters/delegations/progen/pg31/>) by the Director or Scientific Director (SD), of an Institute/Center (IC) that uses animals in its intramural research program. The committee oversees the IC's animal program, facilities and procedures, including the key functions of reviewing and approving requests to use animals in research.
11. **Program Manager** - A government employee experienced in the scientific and technical disciplines addressed in a particular program or project and responsible for developing the technical requirements for a simplified acquisition and assisting the Authorized Purchasing Agent in the administration of the acquisition. The program manager can be an investigator or other individual involved in the animal research activity.
12. **Project Officer** - A government employee experienced in the scientific and technical disciplines addressed in a particular program or project appointed for the awarded contract and responsible for monitoring the technical aspects of the project and assisting the Contracting Officer in the administration of the contract.
13. **Simplified Acquisition** - A contract at or below \$100,000 in which purchases can be made by using one of the following simplified procedures: Purchase orders; Government-wide Commercial Purchase Card; Blanket purchase agreements (BPAs), Federal Acquisition Computer Network (FACNET).

E. Applicability: This policy is applicable to all research and development (R&D) contracts, support contracts and simplified acquisitions that provide services involving animal activities for scientific programs of NIH intramural laboratories. When a government-owned or contractor-owned, contractor-operated facility has a separate assurance on file with OLAW, the same responsibilities under this policy apply to all parties of the facility and subcontractors of the facility who receive PHS funds for activities involving animals.

F. Policy: NIH intramural policy requires that all contracts, including simplified acquisitions, for research, research training, experimentation, and biologic testing involving animals will be conducted in compliance with PHS Policy, the NIH Assurance, AWRs, and local, state, or

federal regulations.

G. Responsibilities:

1. The Deputy Director for Intramural Research, NIH, is responsible for:
 - a. Assuring compliance by all ICs having an intramural research program with the policy stated in section E.
 - b. Reviewing and approving, in consultation with OLAW if necessary, requests for waivers of a provision or provisions of this manual chapter (see section I).
2. The ARAC is responsible for providing a forum for considering issues regarding activities involving animals under contracts and simplified acquisitions serving the intramural program.
3. The IC-ACUC is responsible for:
 - a. Consulting with project officers and program managers during the acquisition planning process, at the concept review phase, or thereafter prior to solicitation to review and approve the specified terms and conditions of the acquisition or the statement of work, as applicable to those components related to the care and use of animals.
 - b. Reviewing and approving changes in the statement of work made between solicitation and award related to the care and use of animals-
 - c. Reviewing copies of animal experimental protocols which have been approved by the contractor's Institutional Animal Care and Use Committee (IACUC) in order to remain cognizant of animal research being funded by the ICs intramural program and to ensure consistency with applicable laws, regulations, and guidelines.
 - d. Reviewing reports of deficiencies by the contractor submitted by the Project Officer, Program Manager or Contracting Officer in order to assure appropriate corrective action is taken when necessary.
 - e. Reviewing requests for waivers to this policy and, if in concurrence, submitting them to the DDIR for written approval (see section I).
4. The Contracting Officer or Authorized Purchasing Agent is responsible for:
 - a. Ensuring review and approval of the specified terms and conditions of the acquisition or the statement of work by the IC-ACUC prior to award.

- b. Ensuring simplified acquisitions, solicitations and contracts are in compliance with HHS Acquisition Regulations (HHSAR) 352.270-9 and otherwise carrying out the responsibilities established in those regulations.
 - c. Reporting apparent deviations from compliance with applicable animal welfare policies and regulations, or deficiencies of the contractor's animal care and use program to the IC-ACUC. If at any time during performance of the contract or service, the Contracting Officer or Authorized Purchasing Agent determines, in consultation with the Office of Laboratory Animal Welfare, National Institutes of Health (NIH), that the Contractor is not in compliance with applicable animal welfare policies and regulations, the Contracting Officer or Authorized Purchasing Agent may immediately suspend, in whole or in part, work and further payments until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the written notice of suspension, the Contracting Officer or Authorized Purchasing Agent may, in consultation with OLAW, NIH, suspend work and further payments for the contract or agreement in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved PHS Animal Welfare Assurances. (see HHSAR 352.270-9)
5. The Project Officer or Program Manager, as applicable, is responsible for:
- a. Submitting the specified terms and conditions of the acquisition or the statement of work to the IC-ACUC for review and approval prior to order placement or award, as applicable. A change to the specified terms and conditions of the acquisition or the statement of work, which involves the care or use of animals, must be reviewed and approved by the IC-ACUC prior to implementation.
 - b. Ensuring animal experimental protocols reviewed and approved by the contractor's IACUC and supported by the contract are within the scope of the specified terms and conditions of the acquisition or the statement of work.
 - c. Receiving copies of approved animal experimental protocols supported by the contractor's IACUC within 20 working days of their approval and submitting them to the IC-ACUC. The Project Officer or Program Manager shall make the approved animal experimental protocols deliverable under the terms of the contract or the specified terms and conditions of the acquisition to meet this time requirement.
 - d. Reporting apparent deviations from compliance with applicable animal welfare policies and regulations or deficiencies of the contractor's animal care and use program to the Contracting Officer or Authorized Purchasing Agent and the IC-ACUC.

H. AAALAC Accreditation Status:

When animals used at a contract site are owned by NIH, either the contractor must have an AAALAC accredited program, or the contract facility and its animal care and use program must become an integral part of NIH's animal care and use program and will be visited and subject to the NIH site-visit proceedings.

I. Assurance Status:

1. Contractor with Assurance on file with OLAW: No further requirements.
2. Contractor without an Assurance: Contractor to be covered by NIH IRP Assurance.
 - a. The IC assumes responsibility for assuring compliance of the contractor's animal care and use program with PHS Policy.
 - b. The IC-ACUC is responsible for reviewing the contractor's program and facilities when conducting semiannual evaluations, and performing other functions, as required by paragraph IV.B. of PHS Policy.
 - c. An inter-institutional agreement is prepared and signed by the proposed contractor, the IC-ACUC chair and the DDIR.

J. Waivers: ICs may request a waiver of a provision or provisions of this manual chapter by submitting a request from the IC-ACUC to the DDIR. Requests will be considered by the DDIR, in consultation with OLAW if necessary. Written waivers may be granted to those providing sufficient justification.

K. Records Retention and Disposal: All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records, Appendix 1, NIH Records Control Schedule," Item: 2600-A-4, Routine Procurement Files.

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

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of

time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

L. Management Controls: The purpose of this manual is to establish responsibility for monitoring the humane care and use of animals involved in research activities which are conducted under contract including simplified acquisitions from elements within the intramural program of NIH.

1. **Office Responsible for Reviewing Management Controls Relative to this Chapter:** Office of Animal Care and Use and the Office of Intramural Research.
2. **Frequency of Review (in years):** Ongoing; at least biennially.
3. **Method of Review:** Alternative Review. The IC Directors or Scientific Directors participate in the Biennial Intramural Self Assessment of Management Controls, through completion of a set of comprehensive checklists of questions. The Office of Intramural Research manages this process.

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

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