NIH Policy Manual

3040-3 - Intramural Acquisitions Involving Animal Research Activities

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Transmittal Notice

1. **Explanation of Material Transmitted:** 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.
2. **Filing Instructions:**

   Remove: Manual Issuance 3040-3, dated 09/03/2004
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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 (IRP).

B. Background

This policy establishes the requirements for institutional oversight of acquisitions, which involve animals by elements of the NIH intramural research program. The authority for this policy is granted by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, herein referred to as "PHS Policy" and the federal Animal Welfare Act Regulations (AWRs).

Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) rules of accreditation state that when animals used at a contractor's 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.

Contract organizations 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 IRP Assurance.** Under unusual circumstances, when it is necessary for an NIH contractor to be included in the NIH Assurance, the Institute or Center (IC) must assume responsibility for compliance of the contractor's animal care and use program with provisions of PHS Policy.

C. 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, AWRs, and local, state, or federal regulations.

D. References

1. HHS Acquisition Regulations (HHSAR) 352.270-5 Care of Laboratory Animals, 48 CFR or as amended : http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=6c1a063b975c50b095427359790ea11d&rgn=div8&view=text&node=48:4.0.1.8.33.2.1.38&idno=48

2. PHS Policy on Humane Care and Use of Laboratory Animals, Revised 2002 (PHS Policy): http://grants.nih.gov/grants/olaw/references/phspol.htm.

3. NIH Manual 3040-2, Animal Care and Use in the Intramural Program

4. Guide for the Care and Use of Laboratory Animals, Institute for Laboratory Animal Research, Commission on Life Sciences, NRC, National Academy Press, 2011 (Guide): http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf

5. NIH Delegations of Authority, Program: General, No 31, NIH Intramural Animal Care and Use Program: http://www.delegations.nih.gov/DOADetails.aspx?id=1673

6. NIH Manual 1743 – Keeping and Destroying Records, Appendix 1

E. Definitions

1. **Accreditation** - The recognition by the AAALAC or other PHS-recognized accrediting body 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.

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 institutional Animal Research Advisory Committee includes the Chair of each IC Animal Care and Use Committee (ACUC) and is appointed by the Deputy Director for Intramural Research (DDIR).
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. **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 includes all types of commitments that obligate the Government to an expenditure of appropriated funds and that, except as otherwise authorized, are in writing. In addition to bilateral instruments, contracts include (but are not limited to) awards and notices of awards, letter contracts, orders, such as purchase orders, under which the contract becomes effective by written acceptance or performance; and bilateral contract modifications. Contracts do not include grants and cooperative agreements covered by 31 USC § 6301 *et seq*.
8. **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 products and services. A contracting officer may be located in an Office of Acquisition, or in a Delegated Office of Acquisition.
9. **Contracting Officer's Representative (COR) –** an individual, including a contracting officer's representative (COR), designated and authorized in writing by the contracting officer to perform specific technical or administrative functions. Typically this is 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.
10. **Institute/Center-Animal Care and Use Committee (IC-ACUC)** - A committee appointed by the Director or Scientific Director (SD), of an IC that uses animals in its intramural research program. The committee oversees the IC's animal program, facilities and procedures, including the key functions of reviewing and approving requests to use animals in research.

11. **Office of Animal Care and Use (OACU)** - The office with authority to act on behalf of the DDIR to ensure that NIH programs and facilities for ACU are in compliance with this policy which is exercised by the Director, OACU.
12. **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.
13. **Simplified Acquisition -** When issued by the Government, means an offer by the Government to buy supplies or services, including research and development, upon specified terms and conditions, using simplified acquisition procedures. Typically under $150,000, purchases can be made using one of the following simplified procedures: Purchase Order; Government-wide Commercial Purchase Card; Blanket purchase agreement (BPA), Task Order/Delivery Order (TO/DO).

F. Responsibilities

1. The Director, OACU, is responsible for:

    a. Assuring compliance by all ICs having an intramural research program with the policy stated in section C.
    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).
    c. Ensuring AAALAC accreditation standards are met when contracts are established.

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. As such, the purchase of custom antibodies will adhere to the Policy Memo: Purchase of Custom Antibodies, October 26, 2011 (PDF Document, 2 pages) rather than the general requirements outlined in this manual chapter.
3. The IC-ACUC (or their designees) are responsible for:

    a. Consulting with CORs and/or program managers during the acquisition planning process,at the concept review phase**,** or thereafter prior to contract award to review terms and conditions of the solicitation including the statement of work (SOW), as applicable to the care and use of animals and notifying the COR of any concerns with the solicitation pertaining to the care and use of animals prior to the final contract award. In addition, the SOW must ensure an approved protocol is in place prior to any animal procedures being conducted.
    b. Providing acknowledgement of the final contract agreement by reviewing the contractor's approved protocol, the SOW or an NIH IC protocol that specifies the animal care and use terms listed in the SOW.
    c. Reviewing reports of deficiencies by the contractor submitted by the COR, Program Manager or Contracting Officer in order to assure appropriate corrective

action is taken when necessary.

d. Reviewing requests for waivers to this policy and, if in concurrence, submitting them to the Director OACU for written approval (see section I).

4. The Contracting Officer is responsible for:

   a. Verifying review and approval of the specified terms and conditions of the solicitation including the statement of work by the IC-ACUC or their designee prior to award.
   b. Reporting potential 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 becomes aware, through the Office of Laboratory Animal Welfare, NIH, that the Contractor is not in compliance with applicable animal welfare policies and regulations, the Contracting Officer 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 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.

5. The COR 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 or their designee 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 Institutional Animal Care and Use Committee (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. 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.
   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 and the IC-ACUC.
   e. Notifying the Director, OACU if an approved contractor does not have a PHS Assurance or is not AAALAC accredited.

G. Procedures

1. AAALAC Accreditation Status:

    a. Contractor with AAALAC accreditation status: no further requirements.
    b. Contractor without AAALAC accreditation status: 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 subject to the NIH accreditation site-visit proceedings. AAALAC will expect documentation of IC ACUC oversight process, such as ACUC site visit reports, MOU/IAA or Standard Operating Procedures which detail contractor daily care and oversight procedures, etc. AAALAC may choose to provide a direct site visit to these programs as part of the NIH IRP site visit or may request key members of the contractor animal program to be available by telephone.
    c. Animal ownership: If the contractor purchases the animals, performs all the experiments/procedures and simply supplies your IC with a product, AAALAC would normally consider those animals 'owned' by the contractor, not NIH, and therefore the contractor would not fall under the NIH IRP accreditation. If NIH purchases the animals, the contractor performs the work and provides a product, the contractor may still 'own' the animals if the transfer of ownership, upon receipt by the contractor, is implicit in the agreement. Ultimately AAALAC will interpret the ownership status based on the relationship established with the contractor and how this is represented by the IC to AAALAC.

2. Assurance Status:

    a. Contractor with Assurance on file with OLAW: When both NIH and the contractor hold Assurances, some latitude is allowed in determining which IACUC will review the proposal. However, NIH always retains primary responsibility for ensuring compliance with PHS Policy. In addition, the contractor must provide to the IC verification of project-specific IACUC approval for conducting the proposed work.
    b. Contractor without an Assurance: Contractor to be covered by NIH IRP Assurance.

        1. The IC assumes responsibility for assuring compliance of the contractor's animal care and use program with PHS Policy.
        2. 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.
        3. An inter-institutional agreement is prepared and signed by the proposed contractor, the IC-ACUC chair and the Director, OACU.

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 Director, OACU on behalf of 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.

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,"Keeping and Destroying Records, Appendix 1, NIH Records Control Schedule, Section 2600, Item A-4 and Section 3000-C- all items that apply. The Section 3000-C retention schedule also applies to OACU forms.

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 chapter 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 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; 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 AAALAC International performs triennial peer review site visits to all NIH components that use animals in their intramural research programs.

4. **Review Reports are sent to:**
   The Deputy Director for Intramural Research and the Director, OACU.