Subpart 370.4—Acquisitions Involving the Use of Laboratory Animals

Parent topic: PART 370—SPECIAL PROGRAMS AFFECTING ACQUISITION

370.400 Scope of subpart.

This subpart applies to all research, research training, biological testing, housing and maintenance, and other activities involving live vertebrate animals conducted under contract. Additional information can be found in Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals *http://grants.nih.gov/grants/olaw/references/phspolicylabanimals.pdf*.

370.401 Policy.

(a) It is HHS policy that contracting activities shall not award a contract involving live vertebrate animals until the Contractor provides acceptable assurance the contract work is subject to initial and continuing review by an appropriate Institutional Animal Care and Use Committee (IACUC) as described in the PHS Policy at IV.B.6 and 7. The contracting officer shall require an applicable Animal Welfare Assurance approved by the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), of each contractor, subcontractor, or institution having responsibility for animal care and use involved in performance of the contract. Normally the assurance shall be approved before award. The contracting officer, on a case-by-case basis, may make award without an approved assurance in consultation with OLAW. For additional information see PHS Policy II., IV.A, and V.B.

(b) The OLAW, NIH, is responsible for negotiating assurances covering all HHS/PHS-supported or HHS/PHS-conducted activities involving the care and use of live vertebrate animals. OLAW shall provide guidance to contracting officers regarding adequate animal care and use, approval, disapproval, restriction, or withdrawal of approval of assurances. For additional information see PHS Policy V.A.

(c) If using live vertebrate animals, HHS policy requires that offerors address the points in the Vertebrate Animal Section (VAS) of the Technical Proposal. Each of the points must be addressed in the VAS portion of the Technical Proposal. For additional information see PHS Policy and use Contract Proposal VAS Worksheet. *http://grants.nih.gov/grants/olaw/references/phspol.htm#InformationRequiredinApplications- ProposalsforAwardsSubmittedtoPHS* and *http://grants.nih.gov/grants/olaw/VAScontracts.pdf*.

370.402 Assurances.

(a) Animal Welfare Assurances may be one of three types:

(1) *Domestic Assurance (DA).* A DA describes the institution's animal care and use program, including but not limited to the lines of authority and responsibility, veterinary care, IACUC composition and procedures, occupational health and safety, training, facilities, and species housed.

A DA listed in OLAW's list of institutions with an approved DA is acceptable for purposes of this policy.

(2) *Inter-institutional Assurance (IA).* The offeror, its proposed subcontractor, or institution shall submit an IA when it does not have a proprietary animal care and use program, facilities to house animals or IACUC, and does not conduct animal research on-site. The offeror will perform the animal activity at an institution with an Animal Welfare Assurance named as a performance site. An IA approval extends to the full period of contract performance (up to 5 years) limited to the specific award or single project.

(3) *Foreign Assurance (FA).* The Foreign Assurance is required for institutions outside the U.S. that receive PHS funds directly through a contract award. The Foreign Assurance also applies to institutions outside the U.S. that receive PHS funds indirectly (named as a performance site). An FA listed in OLAW's list of institutions with an approved FA is acceptable for purposes of this policy.

(b) The contracting officer shall forward copies of proposals selected for negotiation and requiring an assurance to OLAW at *olawdoa@od.nih.gov*, as early as possible to secure the necessary assurances.

(c) A contractor providing animal care services at an institution with an Animal Welfare Assurance, such as a Government-owned, Contractor-operated (GOCO) site, does not need a separate assurance. GOCO site assurances normally cover such contractor services.

370.403 Notice to offerors.

(a) The contracting officer shall insert the provision at 352.270-5a, Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, in solicitations involving live vertebrate animals.

(b) Offerors having a DA on file with OLAW shall submit IACUC approval of the use of animals in the manner required by the solicitation, but prior to award. The date of IACUC approval must not be more than 36 months prior to award.

(c) It is not necessary for offerors lacking an Animal Welfare Assurance to submit assurances or IACUC approval with proposals. OLAW shall contact contractors, subcontractors, and institutions to negotiate necessary assurances and verify IACUC approvals when requested by the contracting officer.

370.404 Contract clause.

The contracting officer shall insert the clause at 352.270-5b, Care of Live Vertebrate Animals, in solicitations, contracts, and orders that involve live vertebrate animals.