

Health and Human Services

370.404

Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), Rev. 1986, Repr. 1996).

[75 FR 21512, Apr. 26, 2010]

370.401 Policy.

(a) It is HHS policy that contracting activities shall not award a contract involving live vertebrate animals until the contractor has given acceptable assurance that the work under the contract will be 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 Full Animal Welfare Assurance or Inter-institutional Agreement/Assurance, approved by the Office of Laboratory Animal Welfare (OLAW), NIH, of each contractor, subcontractor, or cooperating institution having responsibility for animal care and use involved in performance of the contract—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—see PHS Policy V.A.

370.402 Assurances.

(a) Assurances may be one of two following types:

(1) *Full Animal Welfare Assurance (AWA)*. An AWA describes the institution's complete program for the care and use of animals, including but not limited to the facilities, occupational health, training, veterinary care, IACUC procedures and lines of authority and responsibility. An AWA listed in OLAW's list of institutions which have an approved full AWA is acceptable for purposes of this policy.

(2) *Inter-institutional Agreement/Assurance (IAA)*. An IAA describes the arrangements between an offeror and usually a subcontractor where animal activities will occur. An IAA is limited to the specific award or single project.

(b) The Contracting Officer shall forward copies of proposals selected for negotiation and requiring an assurance to the Assurance Branch, Office of Laboratory Animal Welfare, NIH MSC 7507, 6100 Executive Blvd., Room 3B01, Rockville, Maryland 20892, as early as possible to secure the necessary assurances.

(c) A contractor providing animal care services at an assured entity, 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 in 352.270-5(a), Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, in solicitations that involve live vertebrate animals.

(b) Offerors having a full AWA on file with OLAW shall submit IACUC approval of the use of animals in the manner required by instructions for completion of the contract proposal, but prior to the technical review of the proposal. The date of IACUC approval must not be more than 36 months prior to the deadline for proposal submission.

(c) It is not necessary for non-assured offerors to submit assurances or IACUC approval with proposals. OLAW shall contact contractors, subcontractors and cooperating institutions to negotiate necessary assurances and verify IACUC approvals when requested by the Contracting Officer.

[74 FR 62398, Nov. 27, 2009, as amended at 75 FR 21512, Apr. 26, 2010]

370.404 Contract clause.

The Contracting Officer shall insert the clause in 352.270-5(b), Care of Live Vertebrate Animals, in solicitations, contracts, and orders that involve live vertebrate animals.

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