

Health and Human Services

370.400

human subjects. OHRP shall provide guidance to Contracting Officers regarding non-award or termination of a contract due to inadequate assurance or breach of assurance for protection of human subjects.

370.302 Types of assurances.

(a) If an institution does not currently hold an FWA, it should submit one. An FWA listed in OHRP's current "List of Registered Institutional Review Boards (IRBs)/Independent Ethics Committees (IECs) and Approved Assurances" is acceptable for the purposes of this policy.

(b) The OHRP Web site includes links to instructions and the forms for submitting both a domestic and international FWA at: http://www.hhs.gov/ohrp/assurances/assurances_index.html. To expedite approval of a FWA, as well as any update/renewal, the institution shall use the OHRP Electronic Submission System. Once the institution "submits" an electronic file to OHRP, the institution must fax or mail (but not both) a copy of the signature page to initiate the review process. The institution shall mail the FWA to the OHRP, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852, or fax it to OHRP at 240-453-8202 (but not both).

370.303 Notice to offerors.

(a) The Contracting Officer shall insert the provision in 352.270-4(a), Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects, in solicitations that involve human subjects.

(b) Institutions having an OHRP-approved FWA shall certify IRB approval of submitted proposals in the manner required by instructions for completion of the contract proposal; by completion of an OMB Form No. 0990-0263, "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule); or by letter indicating the institution's OHRP-assigned FWA number, the date of IRB review and approval, and the type of review (convened or expedited). The date of IRB approval must not be more than 12 months prior to the deadline for proposal submission.

(c) The Contracting Officer generally will not request FWAs for contractors, subcontractors, or cooperating institutions prior to determination that a contract proposal has been selected for negotiation. When a contractor submits an FWA, it provides certification for the initial contract period. No additional documentation is required. If the contract provides for additional years to complete the project, the contractor shall certify the noncompetitive renewal proposal in the manner described in the preceding paragraph.

370.304 Contract clauses.

(a) The Contracting Officer shall insert the clause in 352.270-4(b), Protection of Human Subjects, in solicitations, contracts, and orders that involve human subjects.

(b) The Contracting Officer shall insert the clause in 352.270-6, Restriction on Use of Human Subjects, in contracts and orders if the contractor has an approved Federal-wide assurance of compliance in place, but cannot certify prior to award that the research has been reviewed and approved by the IRB designated under the contractor's Federal-wide assurance of compliance, because definite plans for involvement of human subjects are not set forth in the proposal (e.g., projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds). Under these conditions, the Contracting Officer may make the award without the requisite certification, as long as the Contracting Officer includes appropriate conditions in the contract or order.

Subpart 370.4—Acquisitions Involving the Use of Laboratory Animals

370.400 Scope of subpart.

This subpart applies to all R & D, research training, biological testing, housing and maintenance, and other activities involving live vertebrate animals conducted under contract (*see*

370.401

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.

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(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.

[75 FR 21512, Apr. 26, 2010]