

## Health and Human Services

370.401

of assurance for protection of human subjects.

### 370.302 Types of assurances.

Assurances may be one of two types:

(a) *Multiple Project Assurance (MPA)*. An MPA describes the oversight procedures applicable to all DHHS-supported human subjects activities within an institution having a significant number of concurrent projects. An MPA listed in OPRR's current "List of Institutions Which Have an Approved MPA" will be considered acceptable for purposes of this policy.

(b) *Single Project Assurance (SPA)*. An SPA describes the oversight procedures applicable to a single DHHS-supported human subjects activity. SPAs may be approved in modified form to meet unusual requirements. SPAs are not solicited from institutions with OPRR approved MPAs. Copies of proposals selected for negotiation and requiring one or more SPAs shall be forwarded to the Human Subjects Assurance Branch, OPRR, NIH MSC 7507, 6100 Executive Blvd., Room 3B01, Rockville, Maryland 20892, as early as possible so that timely action may be taken to secure the SPA(s).

### 370.303 Notice to offerors.

(a) Solicitations shall contain the notice to offerors in 352.270-8(a) whenever contract performance is expected to involve human subjects.

(b) IRB approval of proposals submitted by institutions having an OPRR-approved MPA should be certified in the manner required by instructions for completion of the contract proposal; or by completion of a DHHS Form 310, Protection of Human Subjects Assurance Identification/Certification/Declaration; or by letter indicating the institution's OPRR-assigned MPA 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) SPAs for contractors, subcontractors, or cooperating institutions generally will not be requested prior to determination that a contract proposal has been selected for negotiation. When an SPA is submitted, it provides cer-

tification for the initial contract period. No additional documentation is required. If the contract provides for additional years to complete the project, the noncompetitive renewal proposal shall be certified in the manner described in the preceding paragraph.

### 370.304 Contract clause.

The clause set forth in 352.270-8(b) shall be inserted in all solicitations and resultant contracts involving human subjects.

## Subpart 370.4—Acquisitions Involving the Use of Laboratory Animals

### 370.400 Scope of subpart.

This subpart applies to all research, research training and biological testing activities involving live vertebrate animals conducted under contract (see Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), Rev. 1986, Repr. 1996).

### 370.401 Policy.

(a) It is the policy of the Department of Health and Human Services (DHHS) and the Public Health Service agencies that no contract involving live vertebrate animals shall be awarded until acceptable assurance has been given that the activity 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. An applicable Full Animal Welfare Assurance or Interinstitutional Agreement/Assurance, approved by the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), shall be required 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 OPRR, NIH, is responsible for negotiating assurances covering all DHHS/PHS-supported or DHHS/PHS-conducted activities involving the care and use of live vertebrate animals. Contracting officers shall be guided by

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OPRR 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 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 OPRR's list of institutions which have an approved full AWA will be considered acceptable for purposes of this policy.

(2) *Interinstitutional 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) Copies of proposals selected for negotiation and requiring an assurance shall be forwarded to the Assurance Branch, Division of Animal Welfare, OPRR, NIH MSC 7507, 6100 Executive Blvd., Room 3B01, Rockville, Maryland 20892, as early as possible in order that timely action may be taken 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 because the GOCO site normally covers the contractor services in the GOCO site assurance.

#### 370.403 Notice to offerors.

Solicitations shall contain the notice to offerors in 352.270-9(a) whenever contract performance is expected to involve the use of live vertebrate animals.

(a) For offerors having a full AWA on file with OPRR, IACUC approval of the use of animals shall be submitted 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 review and approval must not be more than 36 months prior to the deadline for proposal submission.]

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(b) Non-assured offerors are not required to submit assurances or IACUC approval with proposals. OPRR will contact contractors, subcontractors and cooperating institutions to negotiate necessary assurances and verify IACUC approvals when requested by appropriate DHHS/PHS staff.

#### 370.404 Contract clause.

The clause set forth in 352.270-9(b) shall be included in all solicitations and resultant contracts involving the care and use of live vertebrate animals.

### Subpart 370.5—Acquisitions Under the Buy Indian Act

#### 370.500 Scope of subpart.

This subpart sets forth the policy on preferential acquisition from Indians under the negotiation authority of the Buy Indian Act. Applicability of this subpart is limited to acquisitions made by or on behalf of the Indian Health Service of the Public Health Service.

#### 370.501 Policy.

(a) The Indian Health Service will utilize the negotiation authority of the Buy Indian Act to give preference to Indians whenever the use of that authority is authorized and is practicable. The Buy Indian Act, 25 U.S.C. 47, prescribes the application of the advertising requirements of section 3709 of the Revised Statutes to the acquisition of Indian supplies. As set out in 25 U.S.C. 47, the Buy Indian Act provides as follows:

So far as may be practicable Indian labor shall be employed, and purchases of the products (including, but not limited to printing, notwithstanding any other law) of Indian industry may be made in open market in the discretion of the Secretary of the Interior.

(b) The functions, responsibilities, authorities, and duties of the Secretary of the Interior for maintenance and operation of hospital and health facilities for Indians and for the conservation of the health of Indians are transferred to the Surgeon General of the United States under the supervision of the Secretary of Health and Human Services, 42 U.S.C. 2001 (a). Accordingly, the Secretary of Health and Human Services is authorized to use the Buy Indian