

## SUBCHAPTER T—HHS SUPPLEMENTATIONS

### PART 370—SPECIAL PROGRAMS AFFECTING ACQUISITION

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AUTHORITY: 5 U.S.C. 301; 40 U.S.C. 486(c).

SOURCE: 66 FR 4262, Jan. 17, 2001, unless otherwise noted.

#### Subpart 370.1—Accessibility of Meetings, Conferences, and Seminars to Persons With Disabilities

##### 370.101 Policy.

(a) It is the policy of HHS that all meetings, conferences, and seminars be

accessible to persons with disabilities. For the purpose of this policy, accessibility is defined as both physical access to meeting, conference, and seminar sites, and aids and services to enable individuals with sensory disabilities to fully participate in meetings, conferences, and seminars.

(b) In regard to acquisition, the policy is applicable to all contracts where the statement of work requires the contractor to conduct meetings, conferences, or seminars that are open to the public or involve HHS personnel, but not to ad hoc meetings that may be necessary or incidental to contract performance.

##### 370.102 Responsibilities.

(a) The Contracting Officer shall include the clause in 352.270-1 in every solicitation and resulting contract when the statement of work requires the contractor to conduct meetings, conferences, or seminars in accordance with 370.101(b).

(b) The Project Officer shall be responsible for obtaining, reviewing, and approving the contractor's plan, which is to be submitted in response to paragraph (a) of the contract clause in 352.270-1. A consolidated or master plan for contracts requiring numerous meetings, conferences, or seminars will be acceptable. The Project Officer, prior to approving the plan, should consult with the OPDIV or other designated organization responsible for ensuring compliance with the Architectural Barriers Act of 1968 and the Americans with Disabilities Act of 1990 to ensure that the contractor's plan meets the accessibility requirements of the contract clause. The Project Officer shall ask the responsible organization to review, and determine the adequacy of, the contractor's plan, and respond to the Project Officer, in writing, within ten (10) working days of receiving the request from the Project Officer.

[71 FR 76514, Dec. 20, 2006]

### Subpart 370.2—Indian Preference in Employment, Training, and Subcontracting Opportunities

#### 370.201 Statutory requirements.

Section 7(b) of the Indian Self-Determination and Education Assistance Act, Public Law 93-638, 88 Stat. 2205, 25 U.S.C. 450e(b), requires:

“Any contract, subcontract, grant, or subgrant pursuant to this Act, the Act of April 16, 1934 (48 Stat. 596), as amended, or any other Act authorizing Federal contracts with or grants to Indian organizations or for the benefit of Indians, shall require that to the greatest extent feasible:

(1) Preferences and opportunities for training and employment in connection with the administration of such contracts or grants shall be given to Indians; and

(b) Preference in the award of subcontracts and subgrants in connection with the administration of such contracts or grants shall be given to Indian organizations and to Indian-owned economic enterprises as defined in section 3 of the Indian Financing Act of 1974 (88 Stat. 77).”

#### 370.202 Applicability.

The Indian Preference clause set forth in 352.270-2 and the Indian Preference Program clause set forth in 352.270-3 have been developed to implement section 7 (b) of Public Law 93-638 for all activities of the Department. The clauses shall be used by any affected departmental contracting activity as follows, except solicitations issued and contracts awarded pursuant to Title I of Public Law 93-638 (25 U.S.C. 450 *et seq.*) are exempted:

(a) The Indian Preference clause (352.270-2) shall be included in each solicitation and resultant contract, regardless of dollar amount:

(1) When the contract is to be awarded pursuant to an act specifically authorizing contracts with Indian organizations; or

(2) Where the work to be performed under the contract is specifically for the benefit of Indians and is in addition to any incidental benefits which might otherwise accrue to the general public.

(b) The Indian Preference Program clause (352.270-3) shall be included in each solicitation and resultant contract when:

(1) The dollar amount of the acquisition is expected to equal or exceed

\$50,000 for nonconstruction work or \$100,000 for construction work;

(2) The Indian Preference clause is to be included in the solicitation and resultant contract; and

(3) The determination is made, prior to solicitation, that the work to be performed under the resultant contract will take place in whole or in substantial part on or near an Indian reservation(s). In addition, the Indian Preference Program clause may be included in any solicitation and resultant contract below the \$50,000 or \$100,000 level for nonconstruction or construction contracts, respectively, but which meet the requirements of paragraphs (b)(2) and (3) of this section 370.202, and, in the opinion of the contracting activity, offer substantial opportunities for Indian employment, training, and subcontracting.

#### 370.203 Definitions.

For purposes of this subpart 370.2, the following definitions shall apply:

(a) *Indian* means a person who is a member of an Indian Tribe. If the contractor has reason to doubt that a person seeking employment preference is an Indian, the contractor shall grant the preference but shall require the individual to provide evidence within thirty (30) days from the Tribe concerned that the person is a member of the Tribe.

(b) *Indian Tribe* means an Indian Tribe, pueblo, band, nation, or other organized group or community, including any Alaska Native Village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688, 43 U.S.C. 1601) which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

(c) *Indian organization* means the governing body of any Indian Tribe or entity established or recognized by such governing body in accordance with the Indian Financing Act of 1974 (88 Stat. 77, 25 U.S.C. 1451).

(d) *Indian-owned economic enterprise* means any Indian-owned commercial, industrial, or business activity established or organized for the purpose of

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profit, provided that such Indian ownership shall constitute not less than 51 percent of the enterprise, and the ownership shall encompass active operation and control of the enterprise.

(e) *Indian reservation* includes Indian reservations, public domain Indian allotments, former Indian reservations in Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of the Alaska Native Claims Settlement Act (85 Stat. 688, 43 U.S.C. 1601 *et seq.*)

(f) *On or near an Indian Reservation* means on a reservation or reservations or within that area surrounding an Indian reservation(s) where a person seeking employment could reasonably be expected to commute to and from in the course of a work day.

#### **370.204 Compliance enforcement.**

(a) The concerned contracting activity shall be responsible for conducting periodic reviews to insure contractor compliance with the requirements of the clauses set forth in 352.270-2 and 352.270-3. These reviews may be conducted with the assistance of the Indian Tribe(s) concerned.

(b) Complaints of noncompliance with the requirements of the clauses set forth in 352.270-2 and 352.270-3 which are filed in writing with the contracting activity shall be promptly investigated and resolved by the contracting officer.

#### **370.205 Tribal preference requirements.**

(a) Where the work under a contract is to be performed on an Indian reservation, the contracting activity may supplement the clause set forth in 352.270-3 by adding specific Indian preference requirements of the Tribe on whose reservation the work is to be performed. The supplemental requirements shall be jointly developed for the contract by the contracting activity and the Tribe. Supplemental preference requirements must represent a further implementation of the requirements of section 7(b) of Public Law 93-638 and must be approved by the affected program director and approved for legal sufficiency by the General Law Division, OGC, or a regional attor-

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ney before being added to a solicitation and resultant contract. Any supplemental preference requirements to be added to the clause in 352.270-3 shall be included in the solicitation and clearly identified in order to insure uniform understanding of the additional requirements by all prospective bidders or offerors.

(b) Nothing in this part shall be interpreted to preclude Tribes from independently developing and enforcing their own tribal preference requirements. Such independently developed tribal preference requirements shall not, except as provided in paragraph (a) of this section, become a requirement in contracts covered under this subpart 370.2, and must not conflict with any Federal statutory or regulatory requirement concerning the award and administration of contracts.

[66 FR 4262, Jan. 17, 2001, as amended at 71 FR 76514, Dec. 20, 2006]

## **Subpart 370.3—Acquisitions Involving Human Subjects**

### **370.300 Scope of subpart.**

This subpart applies to all research and development activities involving human subjects conducted under contract (see 45 CFR 46.102(d) and (f)).

### **370.301 Policy.**

It is the policy of the Department of Health and Human Services (HHS) that no contract involving human subjects shall be awarded until acceptable assurance has been given that the activity will be subject to initial and continuing review by an appropriate Institutional Review Board (IRB) as described in HHS regulations at 45 CFR 46.103. An applicable Federalwide Assurance (FWA), approved by the HHS Office of Human Research Protections (OHRP), shall be required of each contractor, subcontractor, or cooperating institution having responsibility for human subjects involved in performance of the contract. The HHS OHRP is responsible for negotiating assurances covering all HHS-supported or HHS-conducted activities involving human subjects. OHRP shall guide Contracting Officers regarding nonaward or termination of a contract due to inadequate

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assurance or breach of assurance for protection of human subjects.

[71 FR 76514, Dec. 20, 2006]

### 370.302 Types of assurances.

(a) In January 2005, OHRP announced that the FWA would be the only new type of assurance accepted for review and approval by OHRP. Institutions holding an OHRP-approved Multiple Project Assurance (MPA) or Cooperative Project Assurance (CPA) were required to submit an FWA to OHRP for approval by December 31, 2005, if the institution is required to have an OHRP-approved assurance of compliance. Any Inter-Institutional Amendment between an OHRP-approved MPA and an affiliate institution will be deactivated on January 1, 2006 if the affiliate institution has not obtained its own FWA. Single Project Assurances (SPAs) currently approved by OHRP will remain in effect for the duration of the project and through all non-competitive award renewals. 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. The list may be found at <http://ohrp.cit.nih.gov/search/asearch.asp>.

(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](http://www.hhs.gov/ohrp/assurances/assurances_index.html). To expedite the approval of a FWA, as well as any update/renewal, the institution shall use the OHRP Electronic Submission System. Once an electronic file is "submitted" to OHRP, the institution must fax or mail (do not do both) a copy of the signature page to initiate the review process. FWAs shall be mailed to the OHRP, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852, or faxed to OHRP at 240-453-8202 (do not do both).

[71 FR 76514, Dec. 20, 2006]

### 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 OHRP-approved FWA should be certified in the manner required by instructions for completion of the contract proposal; or 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) FWAs 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 FWA is submitted, 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 noncompetitive renewal proposal shall be certified in the manner described in the preceding paragraph.

[71 FR 76515, Dec. 20, 2006]

### 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 (HHS) that no contract involving live vertebrate animals shall be awarded

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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 of Laboratory Animal Welfare (OLAW), 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 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 guide Contracting Officers regarding adequate animal care, and use, approval, disapproval, restriction, or withdrawal of approval of assurances (see PHS Policy V.A.).

[71 FR 76515, Dec. 20, 2006]

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

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(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.

[71 FR 76515, Dec. 20, 2006]

### 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 OLAW, 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.

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

[71 FR 76515, Dec. 20, 2006]

### 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 Act in the acquisition of products of Indian industry in connection with the maintenance and operation of hospital and health facilities for Indians and for the conservation of the health of Indians. This authority has been delegated exclusively to the Indian Health Service and is not available for use by any other HHS component (unless that component is making an acquisition on behalf of the Indian Health Service).

(c) Use of the Buy Indian Act negotiation authority has been emphasized in subsequent legislation, particularly Public Law 94-437 and Public Law 96-537.

#### **370.502 Definitions.**

*Buy Indian contract* means any contract involving activities covered by the Buy Indian Act that is negotiated under the provisions of 41 U.S.C. 252(c) and 25 U.S.C. 47 between an Indian firm and a contracting officer representing the Indian Health Service.

*Indian* means a member of any tribe, pueblo, band, group, village or community that is recognized by the Secretary of the Interior as being Indian or any individual or group of individuals that is recognized by the Secretary of the Interior or the Secretary

of Health and Human Services. The Secretary of Health and Human Services in making determinations may take into account the determination of the tribe with which affiliation is claimed.

*Indian firm* means a sole enterprise, partnership, corporation, or other type of business organization owned, controlled, and operated by one or more Indians (including, for the purpose of sections 301 and 302 of Public Law 94-437, former or currently federally recognized Indian tribes in the State of New York) or by an Indian firm; or a nonprofit firm organized for the benefit of Indians and controlled by Indians (see 370.503(a)).

*Product of Indian industry* means anything produced by Indians through physical labor or by intellectual effort involving the use and application of skills by them.

#### **370.503 Requirements.**

(a) *Indian ownership.* The degree of Indian ownership of an Indian firm shall be at least 51 percent during the period covered by a Buy Indian contract.

(b) *Joint ventures.* An Indian firm may enter into a joint venture with other entities for specific projects as long as the Indian firm is the managing partner. However, the joint venture must be approved by the contracting officer prior to the award of a contract under the Buy Indian Act.

(c) *Bonds.* In the case of contracts for the construction, alteration, or repair of public buildings or public works, performance and payment bonds are required by the Miller Act (40 U.S.C. 270a-270f) and FAR part 28. In the case of contracts with Indian tribes or public nonprofit organizations serving as governmental instrumentalities of an Indian tribe, bonds are not required. However, bonds are required when dealing with private business entities which are owned by an Indian tribe or members of an Indian tribe. Bonds may be required of private business entities which are joint ventures with, or subcontractors of, an Indian tribe or a public nonprofit organization serving as a governmental instrumentality of an Indian tribe. A bid guarantee or bid

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bond is required only when a performance or payment bond is required.

(d) *Indian preference in employment, training and subcontracting.* Contracts awarded under the Buy Indian Act are subject to the requirements of section 7(b) of the Indian Self-Determination and Education Assistance Act 25 U.S.C. 450e, which requires that preference be given to Indians in employment, training, and subcontracting. The Indian Preference clause set forth in 352.270-2 shall be included in all Buy Indian solicitations and resultant contracts. The Indian Preference Program clause set forth in 352.270-3 shall be used as specified in 370.202(b). All requirements set forth in subpart 370.2 which are applicable to the instant Buy Indian acquisition shall be followed by the contracting officer, e.g., sections 370.204 and 370.205.

(e) *Subcontracting.* Not more than 50 percent of the work to be performed under a prime contract awarded pursuant to the Buy Indian Act shall be subcontracted to other than Indian firms. For this purpose, work to be performed does not include the provision of materials, supplies, or equipment.

(f) *Wage rates.* A determination of the minimum wage rates by the Secretary of Labor as required by the Davis-Bacon Act (40 U.S.C. 276a) shall be included in all contracts awarded under the Buy Indian Act for over \$2,000 for construction, alteration, or repair, including painting and decorating, of public buildings and public works, except contracts with Indian tribes or public nonprofit organizations serving as governmental instrumentalities of an Indian tribe. The wage rate determination is to be included in contracts with private business entities even if they are owned by an Indian tribe or a member of an Indian tribe and in connection with joint ventures with, or

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subcontractors of, an Indian tribe or a public nonprofit organization serving as a governmental instrumentality of an Indian tribe.

#### 370.504 Competition.

(a) Contracts awarded under the Buy Indian Act are subject to competition among Indians or Indian concerns to the maximum extent that the Contracting Officer determines is practicable. When competition is determined not to be practicable, a Justification for Other than Full and Open Competition shall be prepared in accordance with 306.303 and subsequently retained in the contract file.

(b) Solicitations must be synopsisized and publicized in *FedBizOpps* at <http://www.fedbizopps.gov> and copies of the synopses sent to the tribal office of the Indian tribal government directly concerned with the proposed acquisition as well as to Indian concerns and others having a legitimate interest. The synopsis must state that the acquisition is restricted to Indian firms under the Buy Indian Act.

[71 FR 76515, Dec. 20, 2006]

#### 370.505 Responsibility determinations.

(a) A contract may be awarded under the Buy Indian Act only if it is first determined that the project or function to be contracted for is likely to be satisfactorily performed under that contract and the project or function is likely to be properly completed or maintained under that contract.

(b) The determination called for by paragraph (a) of this section, to be made prior to the award of a contract, will be made in writing by the contracting officer reflecting an analysis of the standards set forth in FAR 9.104-1.