

SUBCHAPTER M—HHS SUPPLEMENTATIONS

PART 370—SPECIAL PROGRAMS AFFECTING ACQUISITION

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

370.101 Policy.

(a) It is HHS policy 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 SOW/PWS 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 insert the clause in 352.270-1, Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities, in solicitations, contracts, and orders when the SOW/PWS requires the contractor to conduct meetings, conferences, or seminars in accordance with 370.101(b).

(b) The COTR shall obtain, review, and approve 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 is acceptable. The COTR, prior to approving the plan, shall consult with the OPDIV or other designated organization responsible for monitoring 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 COTR shall request the responsible organization to review, and determine the adequacy of, the contractor's plan, and respond to the COTR, in writing, within 10 working days of receiving the request from the COTR.

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

(2) 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 implement section 7(b) of Public Law 93–638 for all HHS activities. Contracting activities shall use the clauses as follows, except that 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 Contracting Officer shall insert the clause in 352.270–2, Indian Preference, in solicitations, contracts, and orders when—

(1) The award is (or will be) made pursuant to an act specifically authorizing such awards with Indian organizations; or

(2) The work to be performed 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 Contracting Officer shall insert the clause in 352.270–3, Indian Preference Program, in solicitations, contracts, and orders 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 included in the solicitation, contract, or order; and

(3) The Contracting Officer makes the determination, prior to solicitation, that performance will take place in whole or in substantial part on or near an Indian reservation(s). In addition, the Contracting Officer may insert the Indian Preference Program clause in solicitations, contracts, and orders 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 Officer, 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 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 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 contracting activity shall conduct periodic reviews to ensure contractor compliance with the requirements of the clauses in 352.270-2 and 352.270-3. The Indian Tribe(s) concerned may assist in the conduct of these reviews.

(b) The Contracting Officer shall promptly investigate and resolve complaints of noncompliance with the requirements of the clauses in 352.270-2 and 352.270-3 that are filed in writing with the contracting activity.

370.205 Tribal preference requirements.

(a) When the contractor will perform work under a contract on an Indian reservation, the Contracting Officer may supplement the clause in 352.270-3 by adding specific Indian preference requirements of the Tribe on whose reservation the work is to be performed. The contracting activity and the Tribe shall jointly develop supplemental requirements for the contract. Supple-

mental preference requirements shall represent a further implementation of the requirements of section 7(b) of Public Law 93-638 and require the approval of the affected program director and OGC-GLD, or a regional attorney, before the Contracting Officer adds them to a solicitation and resultant contract. Any supplemental preference requirements the Contracting Officer adds to the clause in 352.270-3 shall also be part of the solicitation and clearly identified, to ensure uniform understanding of the additional requirements by all prospective bidders or offerors.

(b) Nothing in this part shall 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 370.2, and shall not conflict with any Federal statutory or regulatory requirement concerning the award and administration of contracts.

Subpart 370.3—Acquisitions Involving Human Subjects

370.300 Scope of subpart.

This subpart applies to all R & D activities involving human subjects conducted under contract—see 45 CFR 46.102(d) and (f).

370.301 Policy.

It is HHS policy that the Contracting Officer shall not award a contract involving human subjects until a prospective contractor has provided acceptable assurance 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. The Contracting Officer shall require an applicable Federal-wide assurance (FWA), approved by the HHS Office for Human Research Protections (OHRP), of each contractor, subcontractor, or cooperating institution having responsibility for human subjects involved in performance of a contract. OHRP is responsible for negotiating assurances covering all HHS-supported or HHS-conducted activities involving

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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.

48 CFR Ch. 3 (10-1-12 Edition)

(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*

Health and Human Services

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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.

[75 FR 21512, Apr. 26, 2010]

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. This subpart applies only to acquisitions made by or on behalf of IHS.

370.501 Policy.

(a) The IHS shall 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 specified in 25 U.S.C. 47, the Buy Indian Act provides that, 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) Due to the transfer of authority from the Department of the Interior to HHS, the Secretary of HHS 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 IHS and is not available for use by any other HHS component (unless that component is making an acquisition on behalf of IHS). However, the Buy Indian Act itself does not exempt IHS from meeting the statutorily mandated small business goals.

(c) Subsequent legislation, particularly Public Law 94–437 and Public Law 96–537, have emphasized the use of the Buy Indian Act negotiation authority.

370.502 Definitions.

(a) *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 In-

dian firm and a Contracting Officer representing IHS.

(b) *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 HHS. The Secretary of HHS in making determinations may take into account the determination of the Tribe with which affiliation is claimed.

(c) *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)*).

(d) *Product of Indian industry* means anything produced by Indians through either physical labor or intellectual effort involving the use and application of their skills.

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 Contracting Officer shall approve the joint venture 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, the Miller Act (40 U.S.C. 270a–270f) and *FAR part 28* require performance and payment bonds. Bonds are not required in the case of contracts with Indian tribes or public nonprofit organizations serving as governmental instrumentalities of an Indian Tribe. However, bonds are required when dealing with private business entities that are owned by an Indian Tribe or members of an Indian

Tribe. The Contracting Officer may require bonds of private business entities that 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 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 Contracting Officer shall include the Indian Preference clause specified in 352.270-2 in all Buy Indian solicitations and resultant contracts. The Contracting Officer shall use the Indian Preference Program clause specified in 352.270-3 as prescribed in 370.202(b). The Contracting Officer shall follow all requirements specified in subpart 370.2 which are applicable to a Buy Indian acquisition (e.g., sections 370.204 and 370.205).

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

(f) *Wage rates.* The Contracting Officer shall include a determination of the minimum wage rates by the Secretary of Labor as required by the Davis-Bacon Act (40 U.S.C. 276a) 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 Contracting Officer shall include the wage rate determination 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 subcontractors of, an Indian Tribe or a public nonprofit organi-

zation 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 practicable. When the Contracting Officer determines that competition is not practicable, a JOFOC is required in accordance with 306.303.

(b) The Contracting Officer shall: synopsise and publicize solicitations in FedBizOpps and provide copies of the synopses 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 synopses shall state that the acquisitions are restricted to Indian firms under the Buy Indian Act.

370.505 Responsibility determinations.

(a) The Contracting Officer may award a contract under the Buy Indian Act only if the Contracting Officer determines that the project or function to be contracted is likely to be: satisfactorily performed under that contract; and properly completed or maintained under that contract.

(b) The Contracting Officer shall make the determination specified in paragraph (a) of this section in writing prior to the award of a contract. The determination shall reflect an analysis of the standards set forth in *FAR9.104-1*.

Subpart 370.6—Conference Funding and Sponsorship

370.600 Policy.

It is HHS policy that the conferences it funds or sponsors shall: be consistent with HHS missions, objectives, and policies; represent an efficient and effective use of taxpayer funds; and be able to withstand public scrutiny.

370.601 Funding and sponsorship.

Funding a conference through an HHS contract does not automatically imply HHS (OPDIV/STAFFDIV) conference sponsorship, unless the conference is funded entirely by HHS.

Also, HHS staff attendance or participation at a conference does not imply HHS conference sponsorship. Accordingly, for other than conference contracts funded entirely by HHS, prior to a contractor claiming HHS conference sponsorship, the contractor must provide to the Contracting Officer a written request for permission to claim HHS as the conference sponsor—see 370.602. The OPDIV/STAFFDIV head, or designee, shall approve such requests.

370.602 Contract clause.

To ensure that a contractor:

(a) Properly requests approval to claim HHS as the conference sponsor, where HHS is not the sole provider of conference funding; and

(b) Includes an appropriate Federal funding disclosure and content disclaimer statement on conference materials, the Contracting Officer shall include the clause in 352.270–7, Conference Sponsorship Request and Conference Materials Disclaimer, in solicitations, contracts, and orders that provide funding, in whole or in part, to support a conference.

Subpart 370.7—Acquisitions Under the Leadership Act

370.700 Scope of subpart.

This subpart sets forth the acquisition requirements regarding implementation of HIV/AIDS programs under the President’s Emergency Plan for AIDS Relief under the Leadership Act of 2003, and under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (Emergency Plan reauthorization legislation), which was signed by the President on July 30, 2008.

370.701 Contract clause.

The Contracting Officer shall insert the clause in 352.270–8, Prostitution and

Related Activities, in solicitations, contracts, and orders, and in existing contracts and orders (whenever they are modified to extend the period of performance or add funds, including any options that may be exercised): in connection with the implementation of HIV/AIDS programs under the President’s Emergency Plan for AIDS Relief; or where the contractor will receive funding under the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003. (*Note: See 370.702 and 352.270–9 for the “Non-discrimination for Conscience” provision that must also be included in applicable solicitations.*) In resolving any issues/complaints that offerors/contractors may raise about meeting the requirements specified in the clause, the Contracting Officer shall consult with the Office of Global Health Affairs, Office of the General Counsel, the Project Officer, and other HHS officials, as appropriate.

370.702 Solicitation provision.

The Contracting Officer shall insert the provision in 352.270–9, Non-discrimination for Conscience, in solicitations valued at more than the micro-purchase threshold: in connection with the implementation of HIV/AIDS programs under the President’s Emergency Plan for AIDS Relief; or where the contractor will receive funding under the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003. (*Note: See 370.701 and 352.270–8 for the “Prostitution and Related Activities” clause that must also be included in applicable solicitations, contracts, and orders.*) In resolving any issues/complaints that offerors may raise about meeting the requirements specified in the provision, the Contracting Officer shall consult with the Office of Global Health Affairs, Office of the General Counsel, the Project Officer, and other HHS officials, as appropriate.