

370.204

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 Business and Administrative Law Division, OGC,

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or a regional attorney 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.

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 (DHHS) 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 DHHS regulations at 45 CFR 46.103. An applicable Multiple Project Assurance (MPA) or Single Project Assurance (SPA), 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 human subjects involved in performance of the contract. The OPRR, NIH, is responsible for negotiating assurances covering all DHHS-supported or DHHS-conducted activities involving human subjects. Contracting officers shall be guided by OPRR regarding nonaward or termination of a contract due to inadequate assurance or breach