Subpart 370.3 - Acquisitions Involving Human Subjects

Parent topic: PART 370 - SPECIAL PROGRAMS AFFECTING ACQUISITION

370.300 Scope of subpart.

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

370.301 Policy.

It is the Department of Health and Human Services (HHS) policy that the contracting officer shall not award a contract involving human subjects until the prospective contractor provides assurance that the activity will undergo initial and continuing review by an appropriate Institutional Review Board (IRB) in accordance with HHS regulations at 45 CFR 46.103. The contracting officer shall require a Federal-wide assurance (FWA), approved by the HHS Office for Human Research Protections (OHRP), of each contractor, subcontractor, or institution engaged in human subjects research in performance of a contract. OHRP administers the assurance covering all HHS-supported or HHS-conducted activities involving human subjects.

370.302 Federal-wide Assurance (FWA).

(a) OHRP-Approved FWAs are found at the following Web site: *http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc*.

(b) Normally a contractor, subcontractor, or institution must provide approval of a FWA before a contract is awarded. If a contractor, subcontractor, or institution does not currently hold an approved FWA, it shall submit an explanation with its proposal and an FWA application prior to submitting a proposal. The contracting officer, on a case by case basis, may make award without an approved assurance in consultation with OHRP.

(c) A contractor, subcontractor, or institution must submit all FWAs, including new FWAs, using the electronic submission system available through the OHRP Web site at *http://ohrp.cit.nih.gov/efile/*, unless an institution lacks the ability to do so electronically. If an institution believes it lacks the ability to submit its FWA electronically, it must contact OHRP by telephone or email (see *http://www.hhs.gov/ohrp/assurances/index.html*) and explain why it is unable to submit its FWA electronically.

370.303 Notice to offerors.

(a) The contracting officer shall insert the provision at 352.270-4a, Notice to Offerors, Protection of

Human Subjects, in solicitations that involve human subjects. The contracting officer shall use the clause with its Alternate I when the agency is prescribing a date later than the proposal submission by which the offeror must have an approved FWA.

(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 institutions prior to selecting a contract proposal 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 annually in the manner described in 370.303(b).

(d) For the Food and Drug Administration (FDA), the contracting officer shall insert the provision at 352.270-10, Notice to Offerors - Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required, in solicitations that involve human subjects when the research is subject to RIHSC review and approval.

370.304 Contract clauses.

(a) The contracting officer shall insert the clause at 352.270-4b, Protection of Human Subjects, in solicitations, contracts and orders involving human subjects.

(b) The contracting officer shall insert the clause at 352.270-6, Restriction on Use of Human Subjects, in contracts and orders if the contractor has an approved FWA of compliance in place, but cannot certify prior to award that an IRB registered with OHRP reviewed and approved the research, 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.

(c) For FDA, the contracting officer shall insert the clause at 352.270-11, Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required, in contracts and orders that involve human subjects when the research is subject to RIHSC review and approval.

(d) The contracting officer shall insert the clause at 352.270-12, Needle Exchange, in solicitations, contracts, and orders involving human subjects.

(e) The contracting officer shall insert the clause at 352.270-13, Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research, in solicitations, contracts, and orders involving human subjects.