

Health and Human Services

370.400

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.

(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*