PART 370—SPECIAL PROGRAMS AFFECTING ACQUISITION

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Parent topic: SUBCHAPTER M—HHS SUPPLEMENTATIONS

Subparts 370.1-370.2 [Reserved]

Subpart 370.3—Acquisitions Involving Human Subjects

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.

Subpart 370.4—Acquisitions Involving the Use of Laboratory Animals

370.400 Scope of subpart.

This subpart applies to all research, research training, biological testing, housing and maintenance, and other activities involving live vertebrate animals conducted under contract. Additional information can be found in Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals *http://grants.nih.gov/grants/olaw/references/phspolicylabanimals.pdf*.

370.401 Policy.

(a) It is HHS policy that contracting activities shall not award a contract involving live vertebrate animals until the Contractor provides acceptable assurance the contract work is 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 Animal Welfare Assurance approved by the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), of each contractor, subcontractor, or institution having responsibility for animal care and use involved in performance of the contract. Normally the assurance shall be approved before award. The contracting officer, on a case-by-case basis, may make award without an approved assurance in consultation with OLAW. For additional information 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. For additional information see PHS Policy V.A.

(c) If using live vertebrate animals, HHS policy requires that offerors address the points in the Vertebrate Animal Section (VAS) of the Technical Proposal. Each of the points must be addressed in the VAS portion of the Technical Proposal. For additional information see PHS Policy and use Contract Proposal VAS Worksheet. *http://grants.nih.gov/grants/olaw/references/phspol.htm#InformationRequiredinApplications- ProposalsforAwardsSubmittedtoPHS* and *http://grants.nih.gov/grants/olaw/VAScontracts.pdf*.

370.402 Assurances.

(a) Animal Welfare Assurances may be one of three types:

(1) *Domestic Assurance (DA).* A DA describes the institution's animal care and use program, including but not limited to the lines of authority and responsibility, veterinary care, IACUC composition and procedures, occupational health and safety, training, facilities, and species housed. A DA listed in OLAW's list of institutions with an approved DA is acceptable for purposes of this policy.

(2) *Inter-institutional Assurance (IA).* The offeror, its proposed subcontractor, or institution shall submit an IA when it does not have a proprietary animal care and use program, facilities to house animals or IACUC, and does not conduct animal research on-site. The offeror will perform the animal activity at an institution with an Animal Welfare Assurance named as a performance site. An IA approval extends to the full period of contract performance (up to 5 years) limited to the specific award or single project.

(3) *Foreign Assurance (FA).* The Foreign Assurance is required for institutions outside the U.S. that receive PHS funds directly through a contract award. The Foreign Assurance also applies to institutions outside the U.S. that receive PHS funds indirectly (named as a performance site). An FA listed in OLAW's list of institutions with an approved FA is acceptable for purposes of this policy.

(b) The contracting officer shall forward copies of proposals selected for negotiation and requiring an assurance to OLAW at *olawdoa@od.nih.gov*, as early as possible to secure the necessary

assurances.

(c) A contractor providing animal care services at an institution with an Animal Welfare Assurance, 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 at 352.270-5a, Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, in solicitations involving live vertebrate animals.

(b) Offerors having a DA on file with OLAW shall submit IACUC approval of the use of animals in the manner required by the solicitation, but prior to award. The date of IACUC approval must not be more than 36 months prior to award.

(c) It is not necessary for offerors lacking an Animal Welfare Assurance to submit assurances or IACUC approval with proposals. OLAW shall contact contractors, subcontractors, and institutions to negotiate necessary assurances and verify IACUC approvals when requested by the contracting officer.

370.404 Contract clause.

The contracting officer shall insert the clause at 352.270-5b, Care of Live Vertebrate Animals, in solicitations, contracts, and orders that involve live vertebrate animals.

Subparts 370.5-370.6 [Reserved]

Subpart 370.7—Acquisitions Under the Leadership Act

370.700 Scope of subpart.

This subpart sets forth the acquisition requirements regarding implementation of Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) programs under the President's Emergency Plan for AIDS Relief as established by the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003, as amended (Pub. L. 108-25, Pub. L. 110-293, Pub. L. 113-56).

370.701 Solicitation provision.

The contracting officer shall insert the provision at 352.270-9, Non-Discrimination for Conscience, in solicitations valued at more than the micro-purchase threshold:

(a) In connection with the implementation of HIV/AIDS programs under the President's Emergency

Plan for AIDS Relief established by the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003, as amended; or

(b) Where the contractor will receive funding under the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003, as amended. In resolving any issues or complaints that offerors may raise regarding 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 Program Manager, and other HHS officials, as appropriate.