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.

Parent topic: Subpart 370.3—Acquisitions Involving Human Subjects