1352.235-73 Research involving human subjects - after initial contract award.

As prescribed in 48 CFR 1335.006(d), insert the following clause:

Research Involving Human Subjects - After Initial Contract Award (APR 2010)

(a) No research involving human subjects is currently included in this contract/task order, and no research involving human subjects is permitted under this contract/task order unless expressly authorized, in writing, by the Contracting Officer.

(b) The Federal Policy for the Protection of Human Subjects (the “Common Rule”), adopted by the Department of Commerce at 15 CFR part 27, requires that contractors maintain appropriate policies and procedures for the protection of human subjects in research. The Common Rule defines a “human subject” as a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The term “research” means a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

(c) The Common Rule also sets forth categories of research that may be considered exempt from this policy. These categories are specified at 15 CFR 27.101(b).

(d) In the event that human subjects research involves pregnant women, prisoners, or children, the contractor is also required to follow the guidelines set forth at 45 CFR part 46 subparts B, C and D, as appropriate, for the protection of members of a protected class.

(e) Should research involving human subjects become necessary for carrying out this contract/task order, prior to undertaking or conducting such human subjects research, contractor shall submit the following documentation to the Contracting Officer:

(1) Documentation to verify that contractor has established a relationship with an appropriate Institutional Review Board (“cognizant IRB”). An appropriate IRB is one that is located within the United States and within the community in which the human subjects research will be conducted;

(2) Documentation to verify that the cognizant IRB is registered with the United States Department of Health and Human Services' Office for Human Research Protections (“OHRP”);

(3) Documentation to verify that contractor has a valid Federal-wide Assurance (FWA) issued by the OHRP.

(f) Prior to starting any research involving human subjects, contractor shall submit appropriate documentation to the Contracting Officer for Government institutional review and approval. This documentation may include:

(1) Copies of the human subjects research protocol, advertisements, recruitment material, and informed consent forms approved by the cognizant IRB;

(2) Documentation of approval for the human subjects research protocol, advertisements, recruitment material, and informed consent forms by the cognizant IRB;

(3) Documentation of continuing IRB approval by the cognizant IRB at appropriate intervals as designated by the IRB, but not less than annually; and/or

(4) Documentation to support an exemption for the project from the Common Rule [*Note:* this option is not available for activities that fall under 45 CFR part 46 subpart C].

(g) In addition, if contractor modifies a human subjects research protocol, advertisement, recruitment material, or informed consent form approved by the cognizant IRB, contractor shall submit a copy of all modified material, along with documentation of approval for said modification by the cognizant IRB, to the Contracting Officer for Agency institutional review and approval. Contractor may not implement any IRB-approved modification without written approval by the Contracting Officer.

(h) No work involving human subjects may be undertaken, conducted, or costs incurred and/or charged to the project, until the Contracting Officer approves the required appropriate documentation in writing.

(End of clause)

Parent topic: Subpart 1352.2 - Text of Provisions and Clauses