

1352.235-71 Protection of human subjects - exemption.

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

Protection of Human Subjects (APR 2010)

- (a) Contractor has satisfied the requirements set forth in solicitation # _____, related to the Protection of Human Subjects in research. The Government has determined that the research involving human subjects to be conducted under this contract is exempt from the requirements of the Common Rule for the Protection of Human Subjects. The exemption memorandum executed by the Government and the attachments are hereby incorporated by reference into this contract. If contractor uses an informed consent form for the exempt research, contractor must use the informed consent form contained in the attachments in its conduct of research involving human subjects under this contract.
- (b) If the conditions upon which the exemption is based should change in any way, contractor shall immediately notify the Contracting Officer in writing of the specified change. The Government will review the change and make a determination as to whether the change requires a change to the exemption approval. Contractor shall not proceed until notified in writing of the Contracting Officer's approval. Contractor shall obtain prior written approval from the Contracting Officer for any change to the existing human subjects protocol or informed consent form before proceeding.
- (c) No other research involving human subjects is permitted under this award unless expressly authorized in writing by the Contracting Officer. Such writing will specify the details of the approved research involving human subjects and will be incorporated by reference into this contract.
- (d) The Federal Policy for the Protection of Human Subjects (the "Common Rule"), adopted by the Department of Commerce at 15 CFR Part 27, requires contractors to 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.
- (e) The Common Rule also sets forth categories of research that may be considered exempt from this policy. These categories may be found at 15 CFR 27.101(b).
- (f) In the event the human subjects research involves pregnant women, prisoners, or children, contractor is also required to follow the guidelines set forth at 45 CFR part 46 subpart B, C and D, as appropriate, for the protection of members of a protected class.
- (g) Should additional research involving human subjects be required under the contract, prior to beginning such 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") and is designated as contractor's cognizant IRB;

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

(4) Documentation necessary to support a determination that the research is exempt from the requirements of the Common Rule for the Protection of Human Subjects.

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

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

(2) Documentation of approval for the human subjects research protocol, questionnaires, surveys, advertisements, 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*].

(i) In addition, if the contractor modifies a human subjects research protocol, questionnaire, survey, advertisement, or informed consent form approved by the cognizant IRB, the 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 institutional review and approval. The contractor may not implement any IRB approved modification without written approval by the Contracting Officer.

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](#)