1352.235-72 Protection of human subjects - institutional approval.

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

Protection of Human Subjects - Institutional Approval (APR 2010)

(a) This contract/order includes non-exempt human subjects research that must be conducted pursuant to the requirements of the Federal Policy for the Protection of Human Subjects (the "Common Rule"), adopted by the Department of Commerce at 15 CFR part 27. Contractor has submitted documentation establishing review and approval of the human subjects research protocol, including all informed consent forms, advertisements, and other recruitment materials, by a qualified Institutional Review Board (IRB) that has a current Federal-wide Assurance (FWA) issued by the Department of Health and Human Services (DHHS).

(b) By accepting this contract/order, the contractor certifies the accuracy of the documentation provided to its cognizant IRB and to the Government in support of the human subjects research specified therein. Based upon the contractor's documentation, and following the Government institutional review thereof, the following specific involvement of human subjects in research is hereby approved by the Contracting Officer:

Name of IRB:

(IRB # _____)

Title of IRB Protocol:

Recruiting Letter Approval Date (if appropriate):

Consent Form Approval Date:

Assurance of Compliance Number:

(c) Unless incorporated by written contract modification approved by the Contracting Officer, no other involvement of human subjects in research under this contract may be undertaken or conducted, or costs incurred and/or charged to the project, except as specified in the study plan reviewed and approved by the cognizant IRB and Government. Therefore, if the contractor modifies a human subjects research protocol, advertisement, 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.

Documentation of continuing IRB approval is required each year by the renewal date assigned by the cognizant IRB. Documentation of continuing IRB approval must be submitted to the Government for review and approval as soon as it occurs. Continuing approval of the human subjects research must be obtained from the cognizant IRB and provided to the Government until the research is completed or terminated. The contractor may proceed with previously approved human subjects research, if any, under this contract while the Government is conducting continuing review and approval of the human subjects research protocol. In the event that the Government determines, during the course

of its review, that the human subjects research in this contract is not in compliance with the regulations set forth at 15 CFR part 27, or this contract, the Contracting Officer may take the appropriate enforcement action, including disallowing costs, suspending or terminating the human subjects protocol or the contract, by notifying the contractor in writing.

(d) It is incumbent upon contractor to ensure that continuing IRB review approval occurs in accordance with 15 CFR part 27. In the event that continuing review approval does not occur as set forth by 15 CFR part 27, contractor is to notify the Contracting Officer immediately.

(e) Contractor must report all adverse events to the cognizant IRB and to the Contracting Officer. In the event that adverse events are reported to the cognizant IRB and the Contracting Officer, the Government may suspend this contract pending a full review of the adverse event by the cognizant IRB.

(f) If the conditions upon which IRB approval is based should change in any way, contractor shall immediately notify the Contracting Officer, in writing, of the specified change.

(g) Failure to comply with this contract clause will be considered material noncompliance with the contract, and the Contracting Officer may take appropriate enforcement action, including disallowing costs, suspension or termination of the contract.

(End of clause)

Parent topic: Subpart 1352.2 - Text of Provisions and Clauses