1552.223-70 Protection of human subjects.

As prescribed in 1523.303-70, insert the following contract clause when the contract involves human test subjects.

Protection of Human Subjects March 2015

(a) The contractor shall meet all EPA requirements for studies using human subjects prior to undertaking any work with human subjects in accordance with 40 CFR part 26 and EPA Order 1000.17 A1 Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research. Studies involving intentional exposure of human subjects who are children or pregnant or nursing women are prohibited. Requirements regarding observational studies involving children or pregnant women and fetuses are referenced in subparts C and D of 40 CFR part 26.

(b) The contractor's Institutional Review Board (IRB) approval must state that the contractor's study meets the EPA's regulations at 40 CFR part 26 and EPA Order 1000.17 A1. No work involving human subjects, including recruiting, may be initiated before the EPA has received a copy of the contractor's IRB approval of the project and the EPA has also issued approval. Where human subjects are involved in the research, the contractor must provide evidence of subsequent IRB reviews, including amendments or minor protocol changes, as part of annual reports.

(c) The contractor shall bear full responsibility for the proper and safe performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the government for the acts of the contractor, its employees, sub-contractors, consultants, heirs, assignees, etc.

(d) If at any time during the performance of this contract, the contracting officer determines that the contractor is not in compliance with any of the requirements and/or standards stated in above, the contracting officer may immediately suspend, in whole or in part, work and further payments under this contract until the contractor corrects the noncompliance. The contracting officer may communicate the notice of suspension by telephone with confirmation in writing. If the contractor fails to complete corrective action within the period of time designated in the contracting officer's written notice of suspension, the contracting officer may terminate this contract in whole or in part.

(End of clause)

Parent topic: Subpart 1552.2—Texts of Provisions and Clauses