1252.223-72 Protection of Human Subjects.

As prescribed in 1223.7000(b), insert the following clause:

Protection of Human Subjects (NOV 2022)

(a) The Contractor shall comply with 49 CFR part 11, DOT's regulations for the protection of human subjects participating in activities supported directly or indirectly by contracts from DOT. In addition, the Contractor shall comply with any DOT Operating Administration (OA)-specific policies and procedures on the protection of human subjects.

(b) To demonstrate compliance with the subject DOT regulations and to protect human subjects, the Contractor shall ensure the following:

(1) The Contractor shall establish and maintain a committee competent to review projects and activities that involve human subjects.

(2) The committee shall be assigned responsibility to determine, for each activity planned and conducted, that—

(i) The rights and welfare of subjects are adequately protected;

(ii) The risks to subjects are outweighed by potential benefits; and

(iii) The informed consent of subjects shall be obtained by methods that are adequate and appropriate.

(3) Committee reviews shall be conducted with objectivity and in a manner to ensure the exercise of independent judgment of the members. Members shall be excluded from review of projects or activities in which they have an active role or a conflict of interests.

(4) Continuing constructive communication between the committee and the project directors must be maintained as a means of safeguarding the rights and welfare of subjects.

(5) Facilities and professional attention required for subjects who may suffer physical, psychological, or other injury as a result of participating in an activity shall be provided.

(6) The committee shall maintain records of committee review of applications and active projects, of documentation of informed consent, and of other documentation that may pertain to the selection, participation, and protection of subjects. Detailed records shall be maintained of circumstances of any review that adversely affects the rights or welfare of the individual subjects. Such materials shall be made available to DOT upon request.

(7) The retention period of such records and materials shall be as specified at FAR 4.703.

(c) Periodic reviews shall be conducted by the Contractor to assure, through appropriate administrative overview, that the practices and procedures designed for the protection of the rights and welfare of subjects are being effectively applied.

(d) If the Contractor has or maintains a relationship with a Department of Health and Human Services approved Institutional Review Board (IRB) which can appropriately review this contract in

accordance with the technical requirements and any applicable OA policies and procedures that apply, that IRB will be considered acceptable for the purposes of this contract.

(End of clause)

Parent topic: Subpart 1252.2—Text of Provisions and Clauses