852.235-71 Protection of Human Subjects.

As prescribed at 835.003-72, insert the following clause:

Protection of Human Subjects (DEC 2022)

(a) Research involving human subjects is not permitted under this award unless expressly authorized in writing by the Contracting Officer. Such authorization will specify the details of the approved research involving human subjects and will be incorporated by reference into this contract.

(b) The Federal Policy for the Protection of Human Subjects (the “Common Rule”), adopted by VA (see 38 CFR part 16), 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 and/or testing and evaluation, designed to develop or contribute to generalized knowledge. The Common Rule also sets forth categories of research that may be considered exempt from 15 CFR part 27. These categories may be found at 15 CFR 27.101.

(c) Should research involving human subjects be included in the proposal, prior to issuance of an award, the Contractor shall submit the following documentation to the Contracting Officer:

(1) Documentation to verify that the 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 research will be conducted;

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

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

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

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

(2) Documentation of approval for the 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).

(e) Additionally, if the Contractor modifies a 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 shall not implement any IRB approved modification without written approval by the Contracting Officer.

(f) 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.

(g) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agency or employee of the Government. 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 judgement or otherwise, as an independent Contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

(h) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements, the Contracting Officer may immediately suspend the research and further payments under this contract until the Contractor corrects such noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete the corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OPRR, NIH, terminate this contract and the Contractor's name may be removed from the list of those Contractors with approved Department of Health and Human Services Human Subject Assurances.

(End of clause)

Parent topic: Subpart 852.2—Text of Provisions and Clauses