3452.224-72 Research activities involving human subjects.

As prescribed in 3424.170, insert the following clause in any contract that includes research activities involving human subjects covered under 34 CFR part 97:

Research Activities Involving Human Subjects (OCT 2023)

(a) In accordance with Department of Education (the “Department”) regulations on the protection of human subjects in research, title 34, Code of Federal Regulations, part 97 (the Regulations), Contractors and subcontractors engaged in covered (nonexempt) research activities shall establish and maintain procedures for the protection of human subjects. The Contractor must include the substance of this clause in all subcontracts. In addition, the Contractor shall notify other entities (known to the Contractor) engaged in the covered research activities of their responsibility to comply with the regulations. The definitions in 34 CFR 97.102 apply to this clause. As used in this clause, “covered research” means research involving human subjects that is not exempt under 34 CFR 97.104 and 97.401(b).

(b) If the Department determines that proposed research activities involving human subjects are covered (*i.e.,* not exempt under the regulations), the Contracting Officer (CO) or Contacting Officer's Representative (COR) will require the Contractor to apply for the Federal Wide Assurance from the Office for Human Research Protections, U.S. Department of Health and Human Services, if the Contractor does not already have certification on file. The CO will also require that the Contractor obtain and send to the Department documentation of Institutional Review Board (IRB) review and approval of the proposed research.

(c) Under no condition shall the Contractor conduct, or allow to be conducted, any research activity involving human subjects prior to the Department's receipt of the certification that the proposed research has been reviewed and approved by the IRB (34 CFR 97.103(f)). No research involving human subjects shall be initiated under this contract until the Contractor has provided the CO (or the COR) a properly completed certification form certifying IRB review and approval of the research activity, and the CO or COR has acknowledged the receipt of such certification.

(d) In accordance with 34 CFR 97.109(f)(1), unless IRB or the Department determines otherwise, continuing review of research is not required in the following conditions:

1. Research is eligible for expedited review;

2. Research is reviewed by the IRB in accordance with the limited IRB review as described 34 CFR 97.104(d)(2)(iii); or

3. Research that is part of the IRB-approved study that has progressed to the point that it involves only one or both of the following:

i. data analysis, including analysis of identifiable private information or identifiable biospecimens, or

ii. accessing follow-up clinical data from interventions that subjects would undergo as part of clinical care.

(1) For each activity under this contract that requires continuing review, the Contractor shall submit an annual written representation to the CO or COR stating whether research activities have been reviewed and approved by the IRB within the previous 12 months. The Contractor may use the form titled “U.S. Department of Health and Human Services (HHS) Subpart C Certification Form” for this representation. For multi-institutional projects, the Contractor shall provide this representation on its behalf and on behalf of any subcontractor engaged in research activities for which continuing IRB reviews are required.

(2) If the IRB disapproves, suspends, terminates, or requires modification of any research activities under this contract, the Contractor shall immediately notify the CO in writing of the IRB's action.

(e) The Contractor shall bear full responsibility for performing, as safely as is feasible, all activities under this contract involving the use of human subjects and for complying with all applicable regulations and requirements concerning human subjects. Neither the Contractor, subcontractor, agents of the Contractor, or employees of the Contractor, nor any person, organization, institution, or group of any kind involved in the performance of such activities under this contract, shall be deemed to constitute an agent or employee of the Department or of the Federal government with respect to such activities. The Contractor agrees to 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, subcontractor, or their employees.

(f) Upon discovery of any noncompliance with any of the requirements or standards as stated in this clause, the Contractor shall correct such noncompliance as soon as practicable, typically no later than 1 business day. If the CO determines, in consultation with the Protection of Human Subjects Coordinator, Office of Acquisition, Grants, and Risk Management, Office of Finance and Operations, or the sponsoring office, that the Contractor is not in compliance with the requirements or standards stated in this clause, the CO may suspend work under this contract, in whole or in part, until it is determined that the Contractor has corrected such noncompliance and the CO authorizes the continuation of work.

1. Initial notice of suspension. The initial notice of suspension under this clause may be communicated orally or in writing by the CO.

2. Notice of suspension of work. The CO shall provide written notice of suspension of work under this clause. The notice shall contain the following:

a. The effective date of suspension of work.

b. The requirements and/or standards for which the Contractor is out of compliance.

c. Any special instructions for the suspension of work.

3. Authorization to resume work. If the CO determines that the noncompliance has been remedied and it is in the best interest of the Government, the CO may authorize work to resume under the contract. The CO will provide written notice to the Contractor of such authorization.

(g) Non-compliance with the requirements or standards as stated in this clause may result in the Government termination of this contract for default, in full or in part, in accordance with FAR 49.401. Such termination may be in lieu of or in addition to suspension of work under the contract. Nothing herein shall be construed to limit the Government's right to terminate the contract for failure to fully comply with such requirements or standards.

(h) The Regulations, and related information on the protection of human research subjects, can be found on the Department's protection of human subjects in research website: *https://www2.ed.gov/about/offices/list/ocfo/humansub.html*.

Contractors may also contact the following office to obtain information about the regulations for the protection of human subjects and related policies and guidelines: Protection of Human Subjects Coordinator, U.S. Department of Education Office of Finance and Operations, Office of Acquisition, Grants, and Risk Management, 400 Maryland Avenue SW, Washington, DC 20202–4331. Email: *HumanSubjectsResearch@ed.gov*.

(End of clause)

Parent topic: Subpart 3452.2—Text of Provisions and Clauses