3452.224-71 Notice about research activities involving human subjects.

As prescribed in 3424.170, insert the following provision in any solicitation where a resultant contract will include, or is likely to include, research activities involving human subjects covered under 34 CFR part 97:

Notice About Research Activities Involving Human Subjects (OCT 2023)

(a) Applicable Regulations. In accordance with Department of Education regulations on the protection of human subjects, title 34, Code of Federal Regulations, part 97 (the Regulations), Contractors and subcontractors, engaged in covered (nonexempt) research activities are required to establish and maintain procedures for the protection of human subjects. In addition, the Contractor must notify other entities (known to the Contractor) engaged in the covered research activities of their responsibility to comply with the Regulations.

(b) Definitions.

(1) The Regulations define research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” (34 CFR 97.102(l)). If an activity follows a deliberate plan designed to develop or contribute to generalizable knowledge, it is research. Research includes activities that meet this definition, whether or not they are conducted under a program considered research for other purposes. For example, some demonstration and service programs may include research activities (34 CFR 97.102(l)).

(2) The Regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains, uses, studies, analyzes, or generates identifiable private information. (34 CFR 97.102(e)(1)). Under this definition:

(i) The investigator gathers information about a living person through—

(A) Intervention—Manipulating the subject's environment for research purposes, as might occur when a new instructional technique is tested; or

(B) Interaction—Communicating or interacting with the individual, as occurs with surveys and interviews.

(ii) Identifiable private information is private information about a living person that can be linked to that individual (the identity of the subject is or may be readily ascertained by the investigator or associated with the information).

(iii) Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that an individual can reasonably expect will not be made public (for example, a school health record).

(c) Exemptions. 34 CFR 97.104(d) provides exemptions from the Federal Policy for the Protection of Human Subjects for research activities in which the only involvement of human subjects will be in one or more of the categories set forth in 34 CFR 97.104(d). However, if the research subjects are

children, the exemption at 34 CFR 97.104(d)(2) (*i.e.,* research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior) is modified by 34 CFR 97.401(b), as explained in paragraph (d) of this provision.

(d) Children as research subjects. 34 CFR 97.402(a) defines children as "persons who have not attained the legal age for consent to interventions or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 34 CFR 97.401(b) provides that, if the research involves children as subjects—

(1) The exemption in 34 CFR 97.104(d)(2) does not apply to activities involving—

(i) Survey or interview procedures involving children as subjects; or

(ii) Observations of public behavior of children in which the investigator or investigators will not participate in the activities being observed.

(2) The exemption in 34 CFR 97.104(d)(2) continues to apply, unmodified, by 34 CFR 97.401(b), to—

(i) Educational tests; and

(ii) Observations of public behavior in which the investigator or investigators will not participate in the activities being observed.

(e) Proposal Instructions. An offeror proposing to do research that involves human subjects must provide information to the Department on the proposed exempt and nonexempt research activities. The offeror should submit this information as an attachment to its technical proposal. No specific page limitation applies to this requirement, but the offeror should be brief and to the point.

(1) For exempt research activities involving human subjects, the offeror should identify the exemption(s) that applies and provide sufficient information to allow the Department to determine that the designated exemption(s) is appropriate.

(2) For nonexempt research activities involving human subjects, the offeror must cover the following seven points in the information it provides to the Department. This seven-point narrative can usually be provided in two pages or less:

(i) *Human subjects' involvement and characteristics:* Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as children, children with disabilities, adults with disabilities, persons with mental disabilities, pregnant women, institutionalized individuals, or others who are likely to be vulnerable.

(ii) *Sources of materials:* Identify the sources of research material obtained from or about individually identifiable living human subjects in the form of specimens, records, or data.

(iii) *Recruitment and informed consent:* Describe plans for the recruitment of subjects and the consent procedures to be followed.

(iv) *Potential risks:* Describe potential risks (physical, psychological, social, financial, legal, educational, or other) and assess their likelihood and seriousness. Where appropriate, discuss alternative interventions and procedures that might be advantageous to the subjects.

(v) Protection against risk: Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess the likely effectiveness of such procedures. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of the subjects.

(vi) Importance of knowledge to be gained: Discuss why the risks to the subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

(vii) Collaborating sites: If research involving human subjects will take place at collaborating site(s), name the sites and briefly describe their involvement or role in the research.

(3) If a reasonable potential exists that a need to conduct research involving human subjects may be identified after award of the contract and the offeror's proposal contains no definite plans for such research, the offeror should briefly describe the circumstances and nature of the potential research involving human subjects.

(f) Assurances and certifications.

(1) In accordance with the Regulations and the terms of this provision, all Contractors and subcontractors that will be engaged in research activities involving human subjects shall be required to comply with the requirements for Assurances and Institutional Review Board approvals, as set forth in the contract clause at 3452.224–72 (Research activities involving human subjects).

(2) The Contracting Officer reserves the right to require that the offeror have or apply for the assurance and provide documentation of Institutional Review Board (IRB) approval of the proposed research prior to award. Based on 34 CFR 97.114 Cooperative Research, any institution involved in cooperative research projects (*i.e.,* research projects covered by this Regulation that involve more than one institution) shall enter into a joint review arrangement or rely upon the approval of a single IRB (sIRB) and a reliance agreement for any research conducted within the United States.

(g) Additional information:

(1) 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*.

(2) Offerors may also contact the following office to obtain information about the Regulations, 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 provision)

Parent topic: Subpart 3452.2—Text of Provisions and Clauses