352.270-10 Notice to Offerors - Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.

As prescribed in HHSAR 370.303(d), the Contracting Officer shall insert the following provision:

Notice to Offerors - Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required (DEC 2015)

(a) All Offerors proposing research expected to involve human subjects shall comply with the regulations set forth in 45 CFR part 46, and with the provisions at HHSAR 352.270-4a.

(b) The Offeror shall have an acceptable Assurance of Compliance on file with the Office for Human Research Protections (OHRP), whenever it submits a proposal to the FDA for research expected to involve human subjects. Direct questions regarding Federal-wide Assurance to OHRP. The Offeror's proposal shall include a copy of the acceptable Assurance of Compliance.

(c) After the contract has been awarded, the Contractor shall take the following actions:

(1) The Institutional Review Board (IRB) specified in the Offeror's Assurance of Compliance, hereafter referred to as “the local IRB,” shall review the proposed research protocol. A letter from the local IRB stating that the proposed research protocol has been reviewed and approved, and thus adequately protects the rights and welfare of human subjects involved, or a letter stating that the proposed research is exempt under 45 CFR 46.101(b) shall be submitted to the Contracting Officer.

(2) Upon award, the successful Offeror, hereafter “the Contractor,” shall submit its proposed research protocol to the FDA's Research Involving Human Subjects Committee (RIHSC). The RIHSC or its designee will review and approve the research protocol to assure it adequately protects the rights and welfare of human subjects involved. The RIHSC or designee will also determine whether the proposed research is exempt under 45 CFR 46.101(b). The Contractor shall submit, to the Contracting Officer of record, a copy of the RIHSC's or its designee's letter stating that it reviewed and approved the proposed research protocol.

(d) The Contractor shall not advertise for, recruit, or enroll human subjects, or otherwise commence any research involving human subjects until RIHSC or its designee reviews and approves its research. The Contractor may begin other limited aspects of contract performance prior to receiving RIHSC's or designee's approval of the proposed research protocol. Research involving human subjects may commence immediately upon the Contractor's receipt of RIHSC's or designee's approval; however, the Contractor shall submit a copy of RIHSC's or its designee's approval to the Contracting Officer within three business days of its receipt.

(e) A Contractor's failure to obtain RIHSC's or its designee's approval of its proposed research may result in termination of its contract. However, failure to obtain RIHSC's or its designee's approval during initial review will not automatically result in termination of the contract. Instead, the Contractor may correct any deficiencies identified during the initial RIHSC or designee review and resubmit the proposed research protocol to RIHSC or its designee for a second review. The

Contractor is encouraged to solicit the RIHSC's or its designee's input during the resubmission process.

(f) The Contractor shall seek RIHSC's or its designee's and local IRB review and approval whenever making modifications, amendments or other changes to the research protocol. Such modifications, amendments and changes include, but are not limited to changes in investigators, informed consent forms, and recruitment advertisements. The Contractor may institute changes immediately after receiving both the local IRB and RIHSC or its designee approval (except when necessary to eliminate apparent immediate hazards to the subject); however, the Contractor shall submit a copy of the letter evidencing RIHSC's or its designee's approval of the proposed changes to the Contracting Officer within three business days of its receipt.

(End of provision)

Parent topic: Subpart 352.2 - Texts of Provisions and Clauses