U.S. FOOD & DRUG ADMINISTRATION

Considerations for Human Subjects Research Conducted or Supported by FDA

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Objectives

This presentation provides a basic overview of considerations for research involving human subjects that is funded by the FDA through a Broad Agency Announcement (BAA) Award.

Protection of Human Subjects

FDA is committed to ensuring the protection of the rights, safety and welfare of human subjects in research supported or conducted by the FDA.

Protection of Human Subjects

- Per the BAA, if applicable, Offerors must submit confirmation of an Office for Human Research Protections (OHRP) approved Federal-wide Assurance (FWA) as well as an approved Institutional Review Board (IRB) with their proposal.
- Note that the prime Contractor in any partnership must have an approved FWA and may not rely upon any subcontractor's FWA.

Protection of Human Subjects

- All research involving human subjects conducted or supported by FDA must comply with the requirements at 45 CFR Part 46.
  - With Subpart A known as the “Common Rule”
- If the research is considered FDA-regulated, it must also comply with the applicable FDA requirements (21 CFR Parts 11, 50, 54, 56, 312, 812).
- Additionally, the research should follow other requirements as applicable, including International Council for Harmonisation (ICH) guidelines and other federal and state regulations.

Contractor Responsibilities

When a contract has been awarded, the Contractor is responsible for ensuring that the proposed research protocol has been:

- reviewed and approved by their local Institutional Review Board (IRB) to protect the rights and welfare of human subjects involved, or
- determined to be exempt from the requirements under 45 CFR Part 46.

Documentation of the local IRB approval or exempt determination should be submitted to the Contracting Officer.

FDA Review of Research Activities

After the Contractor provides documentation of their IRB's review and approval or exempt determination, FDA will follow its own institutional procedures for the review of the research to assure that it adequately protects the rights and welfare of human subjects or determine whether the proposed research is exempt from 45 CFR Part 46.

FDA Review of Research Activities

The Contractor shall not commence with any human subject research activities (including advertisement, recruitment, enrollment, etc.) until the Contractor receives documentation from FDA allowing the research to proceed.

Considerations for Project Timelines

Recommend that Offerors allow for sufficient time for their own institutional review processes as well as FDA's review procedures for human subjects research when developing their associated project timeline.

Pre-Submission Questions Relating to the Human Subject Protection Requirements

Offerors should contact the general BAA inbox FDABAA@fda.hhs.gov with any pre-submission questions concerning the human subjects protection requirements in reflected in the Broad Agency Announcement.

Questions Relating to the Human Subject Protection Requirements for the BAA Award

Please consult the FDA Project Lead associated with the research project and the FDA Contracting Officer's Representative when there are technical questions or concerns related to the contractual agreement.


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