



Office of the Human Research Protection Program

Guidance and Procedure: Sponsor Responsibilities for Industry-Sponsored Research (last updated August 16, 2016)

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General Responsibilities of Study Sponsors

Study sponsors along with the researchers and the OHRPP share in the responsibilities for protecting the safety and welfare of human research participants. In order to protect the rights and welfare of human research participants, both the Sponsor and the Institution agree to comply with the ethical standards and regulatory requirements used in human research.

Specific Requirements for Clinical Trial Contracts

There are specific requirements related to the protection of human research participants that are required to be in the clinical trial contract or other funding agreements between the study sponsor and the institution. The contract or funding agreement must specify:

- Who will provide medical care and who will pay for such care in the case of a research-related injury.
- In studies where the sponsor conducts research site monitoring visits or conducts monitoring activities remotely, the sponsor promptly (within 30 days) reports to the PI findings that could affect the safety of participants or influence the conduct of the study.
- When the sponsor has the responsibility to conduct data and safety monitoring, provisions for monitoring the data are in place to ensure the safety of participants and for providing data and safety monitoring reports to the PI.
- Plans for disseminating findings from the research and the roles that researchers and sponsors will play in publication or disclosure of results.
- When participant safety could be directly affected by study results after the study has ended, the researcher or the IRB will be notified of the results in order to consider informing participants.

Reference

Association for the Accreditation of Human Research Protection Programs, Inc®: Evaluation Instrument for Accreditation, 2002-2011: Domain I: Standard 8

Change history:

8/16/2016: Define prompt reporting of certain findings by sponsor as “within 30 days.”