

Investigator Responsibilities

The IRB requires that any investigator proposing the undertaking of a research study, possess the professional qualifications necessary to carry out said research in a safe, responsible and qualified manner.

Responsibilities of the Investigator Include but are not limited to:

1. Complete a Basic Human Participant Protections Education course, and provide evidence of completion of the course to the IRB at the time the investigator submits a new protocol. An investigator will only be required to complete a Basic Human Participant Protections Education tutorial once, but may be asked to provide evidence of the completion of a Basic Human Participant Protections Education tutorial more than once, if there has been an extended time frame (2 years) between the submission of protocols.
2. Ensure the compliance of all sub-investigators, student investigators, and research associates with the decisions, conditions and requirements set forth by the IRB
3. Disclose financial conflicts of interest.
4. Ensure that adequate resources are available to protect human subjects during the proposed research.
5. Obtain IRB approval or an exempt determination before involving human subjects in research.
6. Facilitate PRIOR institutional approval for any research-associated costs, resource utilization, space utilization or use of institutional personnel for clinical duties, data collection or compilation, etc.
7. Complete an application for review (appropriate forms, study protocol, informed consent document investigator's brochure, recruitment materials etc.) of proposed research and obtain IRB approval of any planned activity that meets the definition of research involving human subjects which address all federal requirements.
8. Obtain and document Informed Consent of subjects or their legally authorized representative, prior to their participation in research, unless granted a waiver of informed consent.
9. Practice fair and equitable recruitment processes.

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7. Monitor and take steps to minimize any unanticipated problems or serious adverse events promptly to the IRB

8. Seek clarification and/ or advice regarding any ethical aspects of the research process.

9. Protect and maintain patient protected health information confidentiality during all phases of research, data collection, reporting, and publication. The investigator, sub-investigators, study coordinators, research nurses, and any other persons involved in gathering data for the study must comply with HIPAA standards for privacy of individual protected health information

10. Report the following if using deceased patient information in their proposal:
 1. That they may be obtaining deceased patient information.
 2. The use of the deceased protected health information is for research purposes only

11. Submit an application for renewed approval to the IRB for non-exempt research (along with, progress reports, data safety or monitoring reports, activities, events, and/or information) as requested and in sufficient time to allow for IRB review prior to the expiration date of current approval.

12. Request prior approval to any and all changes in the research process, protocol, or informed consent PROMPTLY to the IRB.

13. Prompt reporting of :
 - serious adverse events and unanticipated problems
 - Potential and confirmed non compliance
 - regular progress reports and process changes
 - Completion of study or closure of research
 - Emergency use of Investigational Drugs or Devices