Investigator Responsibilities

The Clinical Center Medical Staff By-laws delineate who may serve as a principal investigator (PI) on a clinical research protocol. There may be only one PI on a clinical research protocol. The PI must be a health professional qualified, in the judgment of the Institutional Review Board (IRB) and Clinical Director, on the basis of education, training, experience, and demonstrated professional competence, to assume responsibility for the protocol. Consultants and students may not serve as PI or as Medical Advisor on a clinical research protocol.

Principal investigators are responsible for knowing and applying the following:

1. Approval of a protocol is granted to the principal investigator (PI). If the principal investigator ceases to be responsible for the protocol, approval is automatically terminated unless a new principal investigator takes over the study. Should a new principal investigator desire to continue the study, an amendment to the protocol must be submitted and approved by the IRB and study sponsor.
2. The principal investigator must be readily available and part of the Institution.
3. The investigator is responsible for ensuring that all research activities have IRB approval before human subjects are involved and that the research activity follows the approved protocol exactly.
4. The investigator is responsible for informing the research staff of the regulations governing research and of NCI IRB protocol policy.
5. The investigator or designee is responsible for obtaining the informed consent of subjects before the subject is involved in the research.
6. The investigator is responsible for getting IRB approval for any proposed change to the protocol. Approval by the IRB and IND holder is necessary before implementation of any such changes.
7. The investigator is responsible for and must notify the IRB and IND holder of any physical or psychological adverse events experienced by a patient because of participation and also of any emergent or potential problems.
8. The investigator is responsible to notify the IRB of any action (i.e., clinical hold, safety letters) by the IND holder or FDA pertaining to study or agent.
9. The investigator is responsible for obtaining continuing approval from the IRB on a maximum 12-month basis. The IRB can only, by Federal regulations, give approval for up to a period of 12 months. Higher risk research will be given approval periods of less than 12 months.
10. The investigator is responsible for making provision for the safe retention of complete records of human subjects and all research materials.
11. The investigator is responsible for ensuring the confidentiality and security of all information obtained from and about human subjects.
12. In collaborative activities with other institutions, the investigator is responsible for verifying that IRB approval has been obtained from all participating institutions.

Some additional requirements for PI designation apply to projects that fall under the guidelines of the Food and Drug Administration (FDA). The FDA defines an "investigator" as an individual under whose immediate direction a test drug or device is administered or dispensed to a subject. "Subinvestigators" are team members who may help design and conduct the investigation but are not charged with overseeing the investigation. Some team members such as pharmacists, research coordinators, and others who do not directly deal with subjects would not be listed as investigators.

Investigators involved in drug studies must sign an FDA Statement of Investigator Agreement (form FDA-1572), which documents the investigator's commitment to supervise the investigation. No standard agreement exists for device studies. Instead, the device study sponsor prepares a draft agreement and negotiates its terms with the investigator, following the FDA's regulations for investigational devices.