

PRINCIPAL INVESTIGATOR'S RESPONSIBILITIES

A. General Responsibilities of Principal Investigators

The principal investigator (PI) is responsible for personally conducting or supervising the conduct of human-subjects research and for protecting the rights, safety, and welfare of the subjects enrolled in the research. The PI must ensure that all human-subjects research is conducted in an ethical manner and in accordance with all federal, state, and local laws and regulations, institutional policies, and requirements or determinations of the PHRC.

1. Supervising the conduct of human-subjects research

The PI may delegate study-related tasks, but must adequately supervise study personnel to whom tasks are delegated. When supervising the conduct of human-subjects research, the PI must ensure that:

- Study personnel are qualified by training and experience to perform study-related tasks that have been delegated to them;
- Study personnel have an adequate understanding of the research; and
- Study personnel follow the IRB-approved protocol, including the recruitment and consent procedures described in the protocol summary.

The PI should have a plan for supervision and oversight of the research. The intensity of the supervision should take into consideration the study personnel conducting the research, the nature of the research, and the subject population. For more information refer to PHRC guidance [Principal Investigators and Delegation of Study-related Tasks to Co-investigators and Study Staff](#).

2. Protecting the rights, safety, and welfare of research subjects

The PI or other identified qualified individual(s) must be available to provide study subjects with reasonable medical care for any medical problems that arise during participation in the research that are, or could be, related to the research. Additionally, when participation in the research might impact the subject's health and/or medical care, the PI should inform the subject's primary care physician about the subject's participation in the research if the subject has a primary care physician and if the subject agrees to the primary care physician being informed.

When protecting the rights, safety, and welfare of research subjects, the PI must ensure that:

- S/he or other identified, qualified individual(s) provides study subjects with reasonable medical care for any adverse events, including clinically significant laboratory values, related to the research;

- S/he or another specific qualified individual is available to study subjects to answer questions or provide care during the conduct of the research; and
- S/he and all research staff conducting the study adhere closely to the research plan, such as inclusion/exclusion criteria, safety assessments, safety monitoring and reporting of unanticipated problems, and procedures to protect privacy of subjects and confidentiality of identifiable data, in order to minimize risks to subjects.

The PI should not commence the research without adequate resources to protect subjects participating in the research and should stop the research if the resources necessary to protect subjects become unavailable. These resources might include research personnel, space, equipment, time, and availability of medical or psychological care for problems that arise during participation in the research.

B. More Specific Responsibilities of Principal Investigators

The PI must ensure that:

- PHRC approval is obtained prior to initiation of the research;
- The research is conducted in accordance with the PHRC-approved protocol, including, when applicable, the approved recruitment and consent procedures;
- When informed consent is required, informed consent is obtained prior to the initiation of any study-related procedures;
- When written informed consent is required, informed consent is obtained and documented using the current PHRC-approved research consent form;
- When drugs, biological products, and devices are being investigated or used, they are managed and controlled as required by institutional policy and, when applicable, FDA regulations [21 CFR 312](#) and [21 CFR 812](#);
- Changes to the PHRC-approved protocol and/or the research consent form are not initiated without prospective PHRC approval unless necessary to eliminate apparent immediate hazards to the subject;
- Unanticipated problems involving risks to subjects or others (including adverse events) are reported promptly to the PHRC in accordance with [PHRC policy](#);
- When applicable, Data and Safety Monitoring Board/Data Monitoring Committee or other monitoring group reports are submitted promptly to the PHRC for review;
- Continuing review is conducted prior to expiration of PHRC approval in accordance with [PHRC policy](#);
- Should PHRC approval lapse, research procedures, such as recruitment and enrollment of subjects, study procedures on currently enrolled subjects, review of health/medical records, collection of tissue or other samples, or analysis of data, are not conducted until the PHRC re-approves the research or

until special permission is obtained from the PHRC to continue previously enrolled subjects because it is in their best interests to do so;

- When the research has been completed or is being closed out prior to completion, a final continuing review report is submitted to the PHRC;
- Adequate and accurate research records are kept and retained as required by the [PHRC](#) and, when applicable, by the sponsor or FDA; and
- Research records are made available to the PHRC, Partners Quality Improvement Program (QI Program), the sponsor, and when applicable, the Office for Human Research Protections (OHRP), and the Food and Drug Administration (FDA) upon request for monitoring and oversight of the research.

Guidance based on United States. U.S. Dept. of Health and Human Services, Food and Drug Administration, et al. [Guidance for Industry: Protecting the Rights, Safety, and Welfare of Study Subjects – Supervisory Responsibilities of Investigators](#). Draft Guidance May 2007