

Human Subjects Research Programs (HRP)

Overview

Human subjects research is defined as research involving living individuals about whom an investigator obtains data through intervention or interaction with individuals and/or identifiable personal information. This type of research is a major commitment for hospitals that is integrated with the commitment to provide safe, high-quality care. The HRP standards require the governing entity and leaders in academic medical centers with research programs that conduct human subjects research to protect all participating subjects in accordance with international and national principles that govern clinical research. Research protocols involving human subjects are reviewed by an Institutional Review Board (IRB) or other research ethics review mechanism and receive ongoing oversight as necessary. Processes are established to oversee research involving hospital staff conducting the research and all research subjects, regardless of who or what entity sponsors the research. Hospital leaders establish program policies and processes that protect the rights of the human subject participants, identify the program scopes, specify sponsor responsibilities, and describe how the review process is conducted. The program policies also detail how any conflicts of interest applicable to the research and hospital will be managed. Those who conduct research in the organization meet the hospital's qualifications to do so and report all adverse events to the hospital's risk management/quality system in a timely manner. Vulnerable populations are considered when providing information on access to clinical research, clinical investigations, and clinical trials. Hospitals have the opportunity to integrate the research into their overall quality and patient safety program.

Standards

The following is a list of all standards for human subjects research for academic medical centers. The standards in this chapter are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, and Measurable Elements.

Note: The requirements for Standard GLD.09.00 apply to all hospitals that conduct clinical research, regardless of whether the hospital is an academic medical center.

Leadership Accountabilities

HRP.01.00 Hospital leaders are accountable for the protection of human research subjects.

HRP.01.01 Hospital leaders establish the scope of the research program.

HRP.01.02 Hospital leaders establish a policy for sponsors of research to ensure their commitment to the conduct of ethical research.

HRP.01.03 When one or more of the research-related duties and functions of the sponsor are provided through an outside commercial or academic contract research organization, the accountabilities of the outside contract research organization are clearly defined.