Standard HRP.01.01

Hospital leaders establish the scope of the research program.

Intent of HRP.01.01

To ensure that adequate control and resources support all the research within the hospital, hospital leaders must make decisions regarding the scope of research activities, including types and locations. Medical research conducted at the hospital represents varied medical areas and/or specialties within the organization and includes basic, clinical, and health services research. Such research may include clinical trials, therapeutic interventions, development of new medical technologies, and outcomes research, among others. Leaders must set parameters for when a staff member of the hospital may participate as a research subject. Also, leaders are responsible for ensuring that an adequate number of trained staff are available to serve as principal investigators and other members of research teams. The documentation of the required qualifications of staff must include these parameters.

Measurable Elements of HRP.01.01

1. Ⓓ Hospital leaders determine the scope of the research program.
2. Hospital leaders identify the facilities and resources that support the research program.
3. Hospital leaders identify the qualifications of staff permitted to participate in the research program as principal investigators or other members of the research team.
4. Ⓓ There is documentation of the qualifications of staff permitted to participate in the research program.
5. Hospital leaders identify those circumstances in which hospital employees and staff can serve as research subjects.

Standard HRP.01.02

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

Intent of HRP.01.02

Hospital leaders and sponsors are accountable for all elements of the specific research, therefore establishing clear expectations and accountabilities ensures understanding of the commitment to ethically sound research. Hospital leaders and sponsors must share responsibility in the safety of the human subjects and in the protection of their rights. The policies, procedures, and contract agreements established and implemented by the hospital and sponsors must reflect the commitment to the preservation of the rights of the human subject participants, ethical and safe research practices, quality-focused initiatives, and compliance with laws and regulations. Research protocols must reflect that sponsors meet all the requirements, and hospital leaders verify this. Responsibilities of the research sponsor include the initiation, management, and financial commitment of a clinical trial, in addition to ensuring that the research is conducted in accordance with applicable policies and protocols, laws and regulations, and guidelines. Research sponsors must be qualified for the role. Qualifications of a research sponsor may include sponsor, investigator, and/or good clinical practice (GCP) training; and a background, certification, or training in clinical research and proposal preparation.