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.

Measurable Elements of HRP.01.02

1. Ⓓ Hospital leaders establish a written policy for sponsors of research with requirements of accountability for the research, including the following:
   - Compliance with the hospital's policies and processes for monitoring and evaluating the quality, safety, and ethics of the research (*See also* GLD.07.00, ME 1)
   - Research teams must be trained and qualified to conduct the research.
   - Process to protect the privacy and confidentiality of subject data
   - Process to ensure that the research data are reliable and valid, and the results and reporting are statistically accurate, ethical, and unbiased
   - Patient or researcher incentives must not compromise the integrity of the research.
2. Hospital leaders verify that the sponsor of a research protocol must have qualifications for the role.
3. Ⓓ There is documentation confirming that the sponsor understands their responsibility and accountability for the research.

Standard 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.

Intent of HRP.01.03

The sponsor is responsible for the careful selection of a contract research organization, the clear delineation of accountability, and the monitoring of compliance under the contract. When regulations relate to the duties transferred by the sponsor to the contract research organization, the sponsor monitors compliance with those regulations as a part of contract review. The hospital approves the proposed contract with the contract research organization selected by the sponsor.

Human subjects research has many components, some of which a sponsor may choose to contract to an outside person or organization, usually termed a contract research organization. Such components may include recruiting subjects, conducting the research, providing data management, or serving as the research review mechanism.

Measurable Elements of HRP.01.03

1. Ⓓ The hospital establishes and implements a written process to determine the activities and responsibilities of a contract research organization.
2. Ⓓ The duties and functions transferred by the sponsor to the contract research organization are contained in a written contract.
3. Ⓓ The contract specifies that the contract research organization or sponsor is responsible for monitoring and evaluating the quality, safety, and ethics of the research. (*See also* GLD.07.00, ME 1)
4. The sponsor is responsible for monitoring the contract.

Standard HRP.01.04

Hospital leaders implement a process to provide the initial and ongoing review of all human subjects research.

Intent of HRP.01.04

One of the most important processes related to human subjects research is review and monitoring by an independent group of individuals, commonly referred to as an Institutional Review Board (IRB), an ethics committee, or similar designation that monitors all aspects of the research protocol to ensure patient protection and safe research. The composition, scope of responsibilities, and other factors may be described in laws or