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

regulations. The research review process may be contracted to an outside organization such as a regional or national IRB. The policies, procedures, and structure of the research review process are specified by hospital leaders, as well as which functions may or may not be transferred to a contract research organization. Also, hospital leaders are responsible for identifying the types of research that are exempt from this review function and the documentation of the activities of the review group. Documentation of this process is an important component of leaders' responsibility to review, at least on an annual basis, and determine how well the research review process is operating.

Measurable Elements of HRP.01.04

1. Hospital leaders identify and support the structure and operational requirements of the research review process.
2. The research review process complies with applicable laws and regulations.
3. Hospital leaders specify the requirements of entities outside of the hospital that provide all or a portion of the research review process, such as a contract research organization.
4. Hospital leaders ensure that research that is exempt from the research review process is identified.
5. Ⓓ Hospital leaders specify the requirements for documentation of the activities of the research review process.
6. Ⓓ Hospital leaders provide for a review of all research review processes at least annually.

Program Safety

Standard HRP.02.00

The hospital manages conflicts of interest with research conducted at the hospital.

Intent of HRP.02.00

Conflicts of interest can arise from many sources and in many forms for those sponsoring or participating in human subjects research. The conflicts may be financial (such as payment for recruitment of certain types of subjects) or nonfinancial (such as trips to speak at conferences). The research review process can identify and mitigate such conflicts, or the hospital can use or develop another type of mechanism to monitor and mitigate conflicts. The mechanism includes education about what constitutes a conflict and how conflicts can be successfully managed.

Measurable Elements of HRP.02.00

1. Ⓓ The hospital has a written policy to identity and manage conflicts of interest with research conducted at the hospital.
2. Ⓓ The hospital's conflict of interest policy includes a process for managing conflicts of interest, both financial and nonfinancial.
3. The hospital specifies the individuals, committees, and others for whom the requirements apply.
4. The hospital has an ongoing education and monitoring process to ensure compliance with the requirements.

Standard HRP.02.01

The hospital integrates the human subjects research program into the quality and patient safety program of the hospital.