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