

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. ② Hospital leaders specify the requirements for documentation of the activities of the research review process.
6. ② 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. ② The hospital has a written policy to identify and manage conflicts of interest with research conducted at the hospital.
2. 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.