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.

Intent of HRP.02.01

Reporting events related to research protocols can provide vital information toward understanding the overall quality and safety of patient care in the hospital. For example, a significant adverse event when a drug is used for an off-label purpose is important patient safety information that should be part of the hospital's ongoing medication monitoring process.

Human subjects research may involve new types of surgical procedures, the use of new pharmaceuticals or the off-label use of current formulary drugs, the use of adult treatment modalities on pediatric populations, and many other research topics and methodologies. Of primary importance is the inclusion of research activities in the routine processes of the hospital; for example, the ordering, dispensing, and administration process for medications under study. Routine processes also include the reporting of adverse events through the quality and patient safety monitoring processes. Thus, reporting an adverse event related to a hospital patient on a research protocol should be to the quality monitoring mechanism of the hospital as well as to the sponsor of the research or the contract research organization.

All elements of the human subjects research program should be evaluated to determine which of the hospital's quality and safety programs are applicable. Furthermore, any reporting and monitoring processes that are ongoing within the hospital should be included in the research program. Examples include the following:

- Handling and disposal of certain experimental research pharmaceuticals, which should be a component of the management of hazardous materials
- Monitoring and maintenance of medical equipment used in experimental procedures

This should also be the case when some research activities are provided by a contract research organization.

Measurable Elements of HRP.02.01

1. The research program is a component of the hospital's processes to report and act on sentinel events and other adverse events, as well as the processes to learn from near misses (or close calls). (*See also* Sentinel Event Policy and APR.09.00, ME 1)
2. The research program is included in the hospital's programs for hazardous materials management, medical equipment management, and medication management. (*See also* FMS.05.00, ME 1; FMS.07.00, ME 1; MMU.01.00, ME 1)
3. The evaluation of staff participating in the research program is incorporated into the ongoing monitoring processes of professional performance. (*See also* SQE.01.03, ME 2)

Standard HRP.02.02

The hospital informs patients and families about how to gain access to clinical research, clinical investigations, or clinical trials and includes protections for vulnerable populations to minimize potential coercion or undue influence.

Intent of HRP.02.02

Safeguards are put into place through the hospital's research review function to protect vulnerable patients who may be at risk for coercion or undue influence to participate in research projects. Vulnerable patients include children, prisoners, pregnant women, persons with mental disabilities, persons who are economically or educationally disadvantaged, and others who have diminished or no capacity to make informed or voluntary decisions to participate in research. Another group that can be considered a vulnerable population is the hospital staff. Staff may feel pressure to participate; for example, when the principal investigator is their supervisor.

When patients decide to participate in research and grant consent, the individual providing the information and obtaining the consent is noted in the medical record. At times, a research protocol may be altered based on early findings; for example, a drug dose may be changed. Patient consent is obtained again under these