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

and similar circumstances. Risks to patient and/or family safety, rights, and well-being, or risks for coercion or undue influence are reported as adverse, unplanned events. In these circumstances, the IRB process includes the hospital and sponsor's process to prevent further risk when a research trial continues.

Measurable Elements of HRP.02.02

1. The hospital establishes and implements an informed consent process that enables patients to make informed and voluntary decisions about participating in clinical research, clinical investigations, or clinical trials, including the following:
   - How consent for participation will be obtained and documented
   - Under what circumstances consent will be obtained again during the research

   Note: This is accomplished through the research review process.
2. Patients and families are identified and informed about how to gain access to clinical research, clinical investigations, or clinical trials relevant to their treatment needs.
3. Through the research review process, the hospital implements safeguards to protect the safety, rights, and well-being of vulnerable patients, as identified by the hospital, who may be at risk for coercion or undue influence. (*See also* PCC.01.04, ME 4)
4. Through the research review process, the hospital implements safeguards to protect the safety, rights, and well-being of hospital staff who may be at risk for coercion or undue influence.