

**HRP.01.04** Hospital leaders implement a process to provide the initial and ongoing review of all human subjects research.

### Program Safety

**HRP.02.00** The hospital manages conflicts of interest with research conducted at the hospital.

**HRP.02.01** The hospital integrates the human subjects research program into the quality and patient safety program of the hospital.

**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.

## Standards, Intent, and Measurable Elements

### *Leadership Accountabilities*

#### Standard HRP.01.00

Hospital leaders are accountable for the protection of human research subjects.

#### Intent of HRP.01.00

Hospital leaders recognize their responsibility to protect the rights of human research subjects and are committed to promoting a safe environment for these patients.

Human subjects research is a complex and significant endeavor for a hospital. Department/service leaders' commitment to human subjects research is not separate from their commitment to patient care—commitment is integrated at all levels. Hospital leaders recognize the required level of commitment and personal involvement required to advance scientific inquiry. Thus, ethical considerations, good communication, responsible leaders of departments and services, regulatory compliance, and financial and nonfinancial resources are components of this commitment. With differing local regulations, hospital leaders must protect the patient and respect their rights during research, investigation, and clinical trials.

Protecting the rights of human research subjects and promoting a safe environment for these patients requires hospitals to be knowledgeable about and comply with those sources of regulation and professional standards specific for clinical research, such as those from the International Conference on Harmonisation (ICH)/World Health Organization (WHO) Good Clinical Practice (GCP) standards.

#### Measurable Elements of HRP.01.00

1. Hospital leaders establish and promote a code of ethical professional behavior.
2. © Hospital leaders, verbally and in writing, communicate within the hospital its commitment to protect human subjects research participants and support the code of ethical professional behavior.
3. Hospital leaders assume responsibility for patient protection irrespective of the sponsor of the research.
4. © Hospital leaders have a process for budgeting to provide adequate resources for effective operation of the research program.