- Obtains and accepts the parameters of the sponsoring academic program.
- Obtains the complete record of all students and trainees within the hospital.
- Understands and provides the level of supervision for all trainees.
- Integrates students and trainees into the hospital's orientation, quality and patient safety, infection prevention and control, and other programs.

Measurable Elements of GLD.08.00

1. The hospital provides a mechanism(s) for oversight of the training program(s).
2. Ⓓ The hospital has a complete record of all students and trainees within the hospital.
3. Ⓓ The hospital has documentation of the enrollment status, licensure or certifications achieved, and academic classification of the students and trainees.
4. The hospital provides the required level of supervision for each type and level of student and trainee.
5. The hospital provides an opportunity for students and trainees to evaluate the education program and to receive feedback.

Human Subjects Research

Note: Academic medical centers are required to meet these requirements in addition to the "Human Subjects Research Programs" (HRP) chapter.

Standard GLD.09.00

Human subjects research, when provided within the hospital, is guided by laws, regulations, and hospital leaders.

Intent of GLD.09.00

Human subjects research is a complex and significant endeavor for a hospital. Hospital leaders recognize the required level of commitment and personal involvement required to advance scientific inquiry. With differing local regulations, hospital leaders must protect the patient and respect their rights during research, investigation, and clinical trials.

A hospital's commitment to human subjects research is not separate from its commitment to patient care—commitment is integrated at all levels. Thus, ethical considerations, effective communication, responsible leaders, regulatory compliance, and financial and nonfinancial resources are components of this commitment. One such resource is indemnity insurance to compensate patients for adverse events due to the research protocol. Hospital leaders recognize the obligation to protect patients irrespective of the sponsor of the research.

Individuals from the research or other programs are involved in developing the criteria or protocol. Admission to such programs is documented in the patient's medical record and includes the criteria or protocol conditions under which the patient was admitted.

To comply with local laws and regulations, the hospital establishes a committee or identifies a qualified individual(s) to oversee all research in the hospital involving human subjects. A committee or other mechanism such as a hospital-specific or shared Institutional Review Board (IRB) to provide oversight for all such activities in the hospital is established. The hospital develops a statement of purpose for the oversight activities. Oversight activities include the review process for all research protocols, a process to weigh the relative risks and benefits to the subjects, and processes related to the confidentiality and security of the research information.

Measurable Elements of GLD.09.00

1. Hospital leaders identify the official(s) responsible for the development and compliance with human subjects research policies aligned with regulatory and professional requirements.
2. Ⓓ To help the patient determine whether to participate in research, investigation, or clinical trials, the hospital provides the patient with all the following information:
   - An explanation of the purpose and scope of the research
   - The expected duration of the patient's participation
   - A clear description of the procedures to be followed
   - A statement of the potential benefits, risks, discomforts, and side effects
   - Alternative care, treatment, and services available to the patient that might prove advantageous to the patient
3. Ⓓ The hospital documents the following in the research consent form:
   - That the patient received information to help determine whether to participate in the research, investigation, or clinical trial
   - That the patient was informed that refusing to participate in the research, investigation, or clinical trial or discontinuing participation at any time will not jeopardize their access to care, treatment, and services unrelated to the research
   - The name of the person who provided the information and the date the form was signed
   - The patient's right to privacy, confidentiality, and safety (*See also* PCC.01.02, ME 1)
4. Hospital leaders ensure that there is a source of indemnity insurance to compensate patients participating in clinical research who experience an adverse event.
5. Oversight of human subjects research activities includes processes to provide confidentiality and security of research information.