JCI Accreditation Standards for Hospitals and Academic Medical Centers (AMC), 8th Edition

Draft Standards for Field Review

Proposed New Standards and Requirements

Note: This document does not include all standards for Hospitals and Academic Medical Centers (AMC), 8th Edition. The standards in this document are the proposed requirements in the Medical Professional Education (MPE) and Human Subjects Research Programs (HRP) chapters only. To participate in the field review of other chapters of the hospital and AMC standards, please refer back to the JCIA website.

As a reminder, the field review focuses on newly added or significantly revised requirements. To identify the difference:

- Standards, measurable elements, intents, and guidance that are new or have undergone significant changes that have impacted the intent of the requirement are in **RED font**.
- Standards, measurable elements, intents, and guidance that are in **BLACK font** may have undergone changes, but the intents remained the same.

Prior to the publication, a complete summary of changes will be included in the manual along with an updated and complete reference list for each chapter.

Field Review Questionnaire: To participate in the field review of this chapter, please complete the survey below:

https://www.surveymonkey.com/r/ZT9BLSX

Field Review Period: **October 23- November 13, 2023**

Medical Professional Education (MPE)

Overview

Integrating education of medical students and trainees into a hospital's operations needs to be consistent with the hospital's mission, strategic plans, resource allocation, and quality program. The MPE standards emphasize the safety and quality of care provided to patients cared for by trainees and students as part of the hospital's services. The hospital's governing entity and leadership are responsible to ensure that there is appropriate supervision of patient care, treatment, and services delivered in all teaching settings. Ensuring a rich and meaningful experience for medical students and trainees requires many factors in addition to the commitment of the governing entity and hospital leadership.

Trainees and students

- are oriented to the organization and relevant departments;
- understand and participate in quality improvement activities; and
- actively engage in the hospital's culture of safety.

The hospital's governing entity and leadership

- create processes for the direction and accountability of the hospital teaching program medical staff members and other involved staff;
- are knowledgeable about the teaching programs based on timely data-driven information; and
- require improvement processes in the teaching programs related to patient care when opportunities for improvement emerge.

Note: Some measurable elements (MEs) require the organization to have a written policy, procedure, program, or other written document for specific processes. Those MEs are indicated by a P icon after the requirement text. MEs can also require written documentation of compliance, and those requirements are explicitly stated in the ME text. For the standards language in this chapter and in the SME chapter, the following terminology and associated definitions apply:

Medical Staff

*A*ll physicians, dentists, and other professionals who are licensed to practice independently (without supervision) and who provide preventive, curative, restorative, surgical, rehabilitative, or other medical or dental services to patients; or who provide interpretative services for patients, such as pathology, radiology, or laboratory services. All classifications of appointments, all types and levels of staff (employed, honorary, contract, visiting, and private community staff members), are included. Visiting staff include those who are teachers/tutors, and others allowed to provide patient care services temporarily. A hospital must define those other clinical staff, such as "house officers," "hospitalists," "fellows," and "junior doctors," who are no longer in training, but may or may not be permitted by the hospital to practice independently.

The term *medical staff* is thus inclusive of all physicians and other professionals permitted to treat patients with partial or full independence, regardless of their relationship to the hospital (**for example**, employed staff or independent consultants). In some cultures, traditional medicine practitioners, 0. acupuncturists, chiropractors, and others, may be permitted by law and the hospital to practice independently Thus, they are considered medical staff members, and these standards apply in full.

Standards

The following is a list of all standards for this function. They are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, Guidance, and Measurable Elements.

MPE.1 The hospital's governing body and leadership of the hospital approve and monitor the hospital's participation in providing medical education.

MPE.2 The hospital's clinical staff, patient population, technology, and facility are consistent with the goals and objectives of the education program.

MPE.3 Clinical teaching staff are identified, and each staff member's role and relationship to the academic institution is defined.

MPE.4 The hospital has a process for supervision of each type and level of medical student and trainee by a qualified physician.

MPE.5 Medical education provided in the hospital is coordinated and managed through a defined operational mechanism and management structure.

MPE.6 Medical students and trainees comply with all hospital policies and procedures, and all care is provided within the quality and patient safety parameters of the hospital.

MPE.7 Medical trainees who provide care or services within the hospital—outside of the parameters of their academic program—are granted permission to provide those services.

Standards, Intents, Guidance, and Measurable Elements

Standard MPE.1

The hospital's governing body and leadership of the hospital approve and monitor the hospital's participation in providing medical education.

Intent of MPE.1

The governing body and leadership of the hospital are responsible to ensure that the hospital's medical staff program is in alignment with the hospital's mission, strategic plans, resource allocation initiatives, and quality improvement and patient safety program.

Guidance for MPE.1

Integrating education of medical students and trainees (interns, residents, and fellows) into a hospital's operations requires a significant commitment of time, energy, and resources. When the decision to provide medical education involves a network of organizations, the governing entity is fully informed of all the relationships and accountabilities.

The governing entity and leadership of the hospital are also responsible for obtaining, reviewing, and agreeing to the education program parameters of the sponsoring academic program. Parameters include metrics for evaluating the ongoing program operations and patient experience, including patient satisfaction and patient engagement, and also how these might impact the quality of patient care.

A set of metrics is selected and reported to the governing entity and hospital leadership on an annual basis. These metrics are relevant to the education programs within in the hospitals and allow the governing entity and leadership to review the following:

- Scope and activities of the program
- Achievement of program goals
- Any relevant regulatory compliance issues
- Patients and staff satisfaction with the program, including the overall patient experience and the impact the program has on the quality of patient care

The reviews completed by the governing entity and leadership are documented.

Measurable Elements of MPE.1

- ❑ 1. The decision to provide medical education is made by the governing entity and leadership of the hospital, is consistent with the hospital's mission, and is documented.
- ❑ 2. The hospital's governing entity and leadership obtain, review, and accept the parameters of the participating medical school, and this action is documented.
- ❑ 3. The hospital's governing entity and leadership endorse a set of metrics to monitor and evaluate the ongoing operation of medical education programs, and there is documented review of the monitoring data.
- ❑ 4. The hospital's governing entity and leadership review the medical education programs within the hospital at least annually, and the review is documented.
- ❑ 5. The review includes the satisfaction of patients and staff with the clinical care provided under the program.

Standard MPE.2

The hospital's clinical staff, patient population, technology, and facility are consistent with the goals and objectives of the education program.

Intent of MPE.2

The clinical staff of the hospital must be adequate in number and in expertise to advance medical student and trainee education.

Guidance for MPE.2

Providing a rich and meaningful learning experience for medical students and trainees requires many factors, such as support from the governing entity and hospital leadership to provide the resources necessary for program operations and advancement. **For example**, nursing staff numbers support the educational program, and nursing staff understand their relationship to the educational program.

Examples of resources for program operations and advancement include the following:

- Hospital's patient population is sufficient in number to support the education and clinical learning experience
- Adequate classroom space, off-duty study and rest facilities
- Print and online resources to support an effective learning environment
- Adequate opportunities and time for learning and interactions with clinical staff
- Availability of contemporary technology to teach evidence-based health care practices

Measurable Elements of MPE.2

- ❑ 1. There is evidence that the clinical staff of the hospital are adequate in number and have the education, training, and competence to support and advance the education of medical students and trainees.
- ❑ 2. There is evidence that the hospital's patient population is adequate in number and clinical needs to support the education of medical students and trainees.
- ❑ 3. There is evidence that the hospital's facilities, technology, and other resources support the education of medical students and trainees.

Standard MPE.3

Clinical teaching staff are identified, and each staff member's role and relationship to the academic institution is defined.

Intent of MPE.3

All clinical staff who are responsible for medical student and trainee education and supervision are clearly identified so that the medical students, trainees, and other hospital staff understand educational accountabilities and authority.

Guidance for MPE.3

The hospital identifies the roles, responsibilities, and relationship of each clinical teaching staff member to the academic institution for all clinical teaching staff. Hospital staff are educated on the educational roles, accountabilities, and authority of the clinical teaching staff. **For example**, when any hospital staff member has a comment, concern, or other matter related to the educational program or medical students and trainees, they will understand who is accountable for receiving and acting on that information.

The hospital has implemented a process to monitor and maintain current records of academic titles and requirements, including renewal and redesignation,

The relationship of the clinical teaching staff of the hospital to the sponsoring academic institution(s) is clear. **For example**, when academic titles are conferred on clinical staff members, it is clear if titles are earned or honorary, how those titles are to be used, and what the titles mean to the public. The hospital has a recent complete listing of clinical teaching staff with their medical and academic titles. Any requirements for the renewal or redesignation of academic titles are monitored for compliance.

Measurable Elements of MPE.3

- ❑ 1. Clinical teaching staff are identified to hospital staff, and there is a complete list of clinical teaching staff, including both professional and academic titles.
- ❑ 2. Staff are educated about these individuals, their roles, accountabilities, and their authority.
- ❑ 3. The hospital implements a process to monitor and maintain current records of academic titles and requirements for renewal or redesignation.

Standard MPE.4

The hospital has a process for supervision of each type and level of medical student and trainee by a qualified physician.

Intent of MPE.4

Supervision is required to ensure safe patient care and ensure that the training program is a learning experience for the medical student or trainee. . The hospital establishes a defined process for supervision by a medical staff member with appropriate clinical privileges to ensure that the process results in uniform medical student trainee experiences. The process includes the following:

- Required level of supervision is consistent with the level of training within the specialty and level of competence of the medical student and trainee
- Medical student and trainee competence must be demonstrated early in the training program
- Descriptions of the roles, responsibilities, and patient care activities of all participants of graduate education programs

Providing written descriptions of the roles, responsibilities, and patient care activities of the participants of graduate education programs to the medical staff and hospital staff assists to keep uniformity in the process.

Guidance for MPE.4

Each medical student and trainee can assess the level of supervision provided by clinical staff by:

- Understanding the clinical supervision process, including who is to provide the supervision and the frequency of the supervision. **For example**, a medical student understands whether supervision is provided by a resident, the patient's primary physician, or a medical school faculty member.
- Understanding whether the supervision includes daily signing of all notes and orders, signing of the care plan and progress notes every other day, or making a separate entry in the patient's medical record.
- Identifying how the evidence of that supervision is documented, including the frequency and location of documentation.

In addition, the hospital identifies and monitors the expectations for the mentoring/supervision process to ensure a uniform learning experience.

Measurable Elements of MPE.4

- ❑ 1. The hospital establishes a defined process for supervision of each medical student and trainee by a medical staff member with appropriate clinical privileges to provide uniform medical student and trainee experiences.
- ❑ 2. The hospital establishes written descriptions of the roles, responsibilities, and patient care activities of the participants of graduate education programs. The descriptions are as follows:
  - a) Include the process by which the supervisor(s) and graduate education program director make decisions about each participant's progressive involvement and independence in specific patient care activities.
  - b) Are provided to the medical staff providing supervision
  - c) Are provided to each medical student and trainee of the program
  - d) Are provided to the hospital staff
  - e) Identify policies and/or processes that delineate the participants in professional education programs who may write patient care orders, the circumstances under which they may do so, and what entries, if any, must be countersigned by a supervising physician.
  - f) Identify policies and/or processes that delineate the participants in professional education programs to perform part or all of a patient's medical history and physical examination under the supervision of, or through appropriate delegation by, a specific qualified Doctor of Medicine or Doctor of Osteopathy who is accountable for the patient's medical history and physical examination.
  - g) Identify policies and/or processes for when a medical history and physical examination performed by the participants in professional education programs must be validated and countersigned by a physician with appropriate privileges.
- ❑ 3. The level of supervision to be provided is based on the demonstrated competency of the medical student and trainee.
- ❑ 4. There is evidence that each medical student and trainee understands the level, frequency, and documentation of his or her supervision.
- ❑ 5. Health records are reviewed for compliance with the documentation requirements and frequency.

Standard MPE.5

Medical education provided in the hospital is coordinated and managed through a defined operational mechanism and management structure.

Intent of MPE.5

Medical education programs in hospitals require an effective management structure and a commitment of staff time for their coordination and daily operation.

Guidance for MPE.5

The agreements between the hospital and the medical school are established and monitored. There is a current, accurate list of all medical students and trainees in the hospital. The hospital identifies the minimum documentation requirements for each medical student and trainee. Documentation for a medical student may be limited depending on their enrollment status and current level of training. Accommodations may be necessary to meet specific needs of the training program. **For example,** medical student scheduling conflicts, family obligations, imbalanced competencies and specialties between clinical teaching staff and medical students and trainees. When an academic program is sponsored by the hospital, it is determined how and where these activities are conducted.

Measurable Elements of MPE.5

- ❑ 1. The operational structure for medical education in the hospital has been established and is fully operational.
- ❑ 2. The management structure for medical education in the hospital has been determined and implemented.
- ❑ 3. There is a complete and current list of all medical students and trainees in the hospital.
- ❑ 4. For each medical student and trainee, there is documentation of at least:
  - a) Enrollment status
  - b) Academic classification
  - c) Any required licensure or certification
  - d) Reports of medical student and trainee achievements
  - e) Identification of medical student and trainee competencies
  - f) Any known factors that will require accommodation
  - g) Any known factors that may influence the level of supervision required

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Standard MPE.6

Medical students and trainees comply with all hospital policies and procedures, and all care is provided within the quality and patient safety parameters of the hospital.

Intent of MPE.6

Training programs and their students are a critical factor in overall quality of care and patient safety.

Guidance for MPE.6

Individuals providing medical student and trainee supervision must ensure that all medical students and trainees can demonstrate knowledge of these quality and safety programs and are included in the evaluation process.

Each medical student and trainee receives basic education on quality and patient safety in their respective academic program. To achieve this, the hospital must:

- have a planned and deliberate program to introduce quality and patient safety concepts
- support the medical students and trainees in complying with relevant policies and guidelines
- include medical students and trainees in all quality and safety monitoring programs.

Examples of quality and patient safety education for the medical students and trainees' initial orientation and ongoing training and evaluation would include:

- Compliance with the International Patient Safety Goals
- Required clinical practice guidelines
- Surgical time-out procedures
- Medication-ordering policies

- Other mechanisms to reduce variation in care processes, and thus reduce the risk in those processes

Measurable Elements of MPE.6

❑ 1. All medical students and trainees are provided an orientation that includes at least the following:
   a) Hospital quality and patient safety program
   b) Infection prevention and control program
   c) Medication safety program
   d) International Patient Safety Goals
   e) Other required hospital orientation, including at the department and unit level
   f) Ongoing required education

❑ 2. Medical students and trainees are included in the data collection for the hospital's quality monitoring programs.

❑ 3. Those supervising medical students and trainees ensure that the medical students and trainees are knowledgeable of the programs and participate in the programs.

❑ 4. Medical students and trainees can demonstrate knowledge of these programs.

❑ 5. Those supervising medical students and trainees consider compliance with these programs in their evaluation of medical student and trainee performance.

Standard MPE.7

Medical trainees who provide care or services within the hospital—outside of the parameters of their academic program—are granted permission to provide those services.

Intent of MPE.7

The laws and regulations in many countries permit trainees, as they advance in their program, to provide services to the hospital outside of their academic program. **For example**, a trainee may provide medical care in the hospital's emergency department in evenings or on weekends or may function as the "house doctor" during the night shift.

Guidance for MPE.7

If a medical trainee is granted permission to provide services outside of their academic program, the individual trainee must be evaluated and given permission to provide those services through the normal established processes for such professionals as described in the Staff Qualifications and Education (SQE) standards. Any approved services provided by a medical trainee outside their academic program, is then evaluated as required by the SQE standards.

Measurable Elements of MPE.7

❑ 1. The hospital determines what types of trainees and under which circumstances trainees can be hired or otherwise engaged by the hospital to provide patient care or other services.

❑ 2. Trainees providing such services are granted permission through credentialing and privileging, a job description, or other relevant process for the services being provided.

❑ 3. Trainees providing such services are evaluated for the services being provided.

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**Not a complete literature review*

Human Subjects Research Programs (HRP)

Overview

Human subjects research is defined as research involving living individuals about whom an investigator obtains data through intervention or interaction with individuals and/or identifiable personal information. This type of research is a major commitment for hospitals that is integrated with the commitment to provide safe, high-quality care. The HRP standards require the governing entity and leadership in academic medical centers with research programs that conduct human subject research to protect all participating subjects in accordance with international and national principles that govern clinical research. Research protocols involving human subjects are reviewed by an Institutional Review Board (IRB) or other research ethics review mechanism and receive ongoing oversight as necessary. Processes are established to oversee research involving hospital staff conducting the research and all research subjects, regardless of who or what entity sponsors the research. Hospital leadership establishes program policies and processes that protect the rights of the human subject participants, identify the program scopes, sponsor responsibilities, how the review process is conducted, as well as any conflicts of interest applicable to the research and hospital. Those who conduct research in the organization meet the hospital's qualifications to do so and report all adverse events to the hospital's risk management/quality system in a timely manner. Vulnerable populations are considered when providing information on access to clinical research, clinical investigations, and clinical trials. Hospitals have the opportunity to integrate the research into their overall quality and patient safety program.

Standards

The following is a list of all standards for human subjects research for academic medical centers. The standards in this chapter are presented here for your convenience without their intent statements or measurable elements. For more information about these standards, please see the next section in this chapter, Standards, Intents, Guidance, and Measurable Elements.
Note: The requirements for Standard GLD.14 apply to all hospitals who conduct clinical research, regardless of whether the hospital is an academic medical center.

HRP.1 Hospital leadership is accountable for the protection of human research subjects.

HRP.2 Hospital leadership establishes the scope of the research program.

HRP.3 Hospital leadership establishes a policy for sponsors of research to ensure their commitment to the conduct of ethical research.

HRP.3.1 When one or more of the research-related duties and functions of the sponsor are provided through an outside commercial or academic contract research organization, the accountabilities of the outside contract research organization are clearly defined.

HRP.4 Hospital leadership implements a process to provide the initial and ongoing review of all human subjects research.

HRP.5 The hospital manages conflicts of interest with research conducted at the hospital.

HRP.6 The hospital integrates the human subjects research program into the quality and patient safety program of the hospital.

HRP.7 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, Intents, Guidance, and Measurable Elements

Standard HRP.1

Hospital leadership is accountable for the protection of human research subjects.

Intent of HRP.1

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

Guidance for HRP.1

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 (see Endnotes at the end of this chapter).

Measurable Elements of HRP.1

- ❑ 1. Hospital leadership establishes and promotes a code of ethical professional behavior.
- ❑ 2. Hospital leadership, verbally and in writing, communicates within the hospital its commitment to protect human subjects research participants and support the code of ethical professional behavior.
- ❑ 3. Hospital leadership assumes responsibility for patient protection irrespective of the sponsor of the research.
- ❑ 4. Hospital leadership has a process for budgeting to provide adequate resources for effective operation of the research program.

Standard HRP.2

Hospital leadership establishes the scope of the research program.

Intent of HRP.2

To ensure that adequate control and resources support all the research within the hospital, hospital leadership must make decisions regarding the scope of research activities, including types and locations.

Guidance for HRP.2

Medical research conducted at the hospital represents varied medical areas and/or specialties within the organization and includes basic, clinical, and health services research. Such research may include clinical trials, therapeutic interventions, development of new medical technologies, and outcomes research, among others. Leadership is also responsible for ensuring an

adequate number of trained staff to serve as principal investigators and other members of research teams. There is documentation of the required qualifications.

Leadership must set parameters for when a staff member of the hospital may participate as a research subject. Also, leadership is responsible for ensuring an adequate number of trained staff are available to serve as principal investigators and other members of research teams. The documentation of the required qualifications of staff must include these parameters.

Measurable Elements of HRP.2

- ❑ 1. Hospital leadership determines the scope of the research program.
- ❑ 2. Hospital leadership identifies the facilities and resources that support the research program.
- ❑ 3. Hospital leadership identifies the qualifications of staff permitted to participate in the research program as principal investigators or other members of the research team.
- ❑ 4. There is documentation of the qualifications of staff permitted to participate in the research program.
- ❑ 5. Hospital leadership identifies those circumstances in which staff can serve as research subjects.
- 6. 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:
  a) How consent for participation will be obtained and documented
  b) Under which circumstances consent will be obtained again during the research

  Note: This is accomplished through the research review process.

Standard HRP.3

Hospital leadership establishes a policy for sponsors of research to ensure their commitment to the conduct of ethical research.

Intent of HRP.3

Sponsors are accountable for all elements of the specific research, therefore establishing clear expectations and accountabilities ensures understanding of the commitment to ethically sound research.

Guidance for HRP.3

Hospital leadership and sponsors must share responsibility in the safety of the human subjects and in the protection of their rights. The policies, procedures, and contract agreements established and implemented by the hospital and sponsors must reflect the commitment to the preservation of the rights of the human subject participants, ethical and safe research practices, quality-focus initiatives, and compliance with laws and regulations.

Measurable Elements of HRP.3

- ❑ 1. Hospital leadership establishes a policy for sponsors of research with requirements of accountability for the research, including the following:
  a) Compliance with the hospital's policies and processes for monitoring and evaluating the quality, safety, and ethics of the research
  b) Research teams must be trained and qualified to conduct the research
  c) Process to protect the privacy and confidentiality of subject data
  d) Process to ensure that the research data are reliable and valid, and the results and reporting are statistically accurate, ethical, and unbiased.
  e) Patient or researcher incentives must not compromise the integrity of the research.

- ❑ 2. Hospital leadership verifies that the sponsor of a research protocol must be qualified for the role.
- ❑ 3. There is documentation confirming that the sponsor understands their responsibility and accountability for the research.

Standard HRP.3.1

When one or more of the research-related duties and functions of the sponsor are provided through an outside commercial or academic contract research organization, the accountabilities of the outside contract research organization are clearly defined.

Intent of HRP.3.1

The hospital and sponsor are responsible for the careful selection of a contract research organization, the clear delineation of accountability, and the monitoring of compliance under the contract. When regulations relate to the duties transferred by the sponsor to the contract research organization, the sponsor monitors compliance with those regulations as a part of contract review.

Guidance for HRP.3.1

Human subjects research has many components, some of which a sponsor may choose to contract to an outside organization, usually termed a contract research organization. Such components may include recruiting subjects, conducting the research, providing data management, or serving as the research review mechanism.

Measurable Elements of HRP.3.1

- ❑ 1. The hospital establishes and implements a process to determine the activities and responsibilities of a contract research organization.
- ❑ 2. The duties and functions transferred by the sponsor to the contract research organization are contained in a written contract.
- ❑ 3. The contract specifies that the contract research organization or sponsor is responsible for monitoring and evaluating the quality, safety, and ethics of the research.
- ❑ 4. The sponsor is responsible for monitoring the contract.

Standard HRP.4

Hospital leadership implements a process to provide the initial and ongoing review of all human subjects research.

Intent of HRP.4

One of the most important processes related to human subjects research is review and monitoring by an independent group of individuals, commonly referred to as an Institutional Review Board (IRB), an ethics committee, or similar designation that monitors all aspects of the research protocol to ensure patient protection and safe research.

Guidance for HRP.4

The composition, scope of responsibilities, and other factors may be described in laws or regulations. This research review process may be contracted to an outside organization such as a contract research organization. The policies, procedures, and structure of this research review process are specified by hospital leadership, as well as which functions may or may not be transferred to a contract research organization. Also, hospital leadership is 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 leadership's responsibility to review, at least on an annual basis, and determine how well the research review process is operating.

Measurable Elements of HRP.4

- ❑ 1. Hospital leadership identifies and supports the structure and operational requirements of the research review process.
- ❑ 2. The research review process complies with applicable laws and regulations.
- ❑ 3. Hospital leadership specifies 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 leadership ensures that research that is exempt from the research review process is identified.
- ❑ 5. Hospital leadership specifies the requirements for documentation of the activities of the research review process.
- ❑ 6. Hospital leadership provides for a review of all research review processes at least annually.

Standard HRP.5

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

Intent of HRP.5

Conflicts of interest can arise from many sources and in many forms for those sponsoring or participating in human subjects research.

Guidance for HRP.5

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.5

- ❑ 1. The hospital has policy to identity and manage conflicts of interest with research conducted at the hospital.
- ❑ 2. The hospital's COI 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.6

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

Intent of HRP.6

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.

Guidance for HRP.6

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 process 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:

- 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.6

- ❑ 1. The research program is a component of the hospital's processes to report and act on sentinel events, adverse events of other types, and the processes to learn from near misses (or close calls).
- ❑ 2. The research program is included in the hospital's programs for hazardous materials management, medical equipment management, and medication management.
- ❑ 3. The evaluation of staff participating in the research program is incorporated into the ongoing monitoring processes of professional performance.

Standard HRP.7

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.7

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.

Guidance for HRP.7

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 staff of the hospital. 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.

Measurable Elements of HRP.7

- ❑ 1. 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.
- ❑ 2. 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.

❑ 3. 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.

References

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Endnotes

International Conference on Harmonisation (ICH)/World Health Organization (WHO) Good Clinical Practice (GCP) standards

Clinical studies should be carried out according to International Conference on Harmonisation (ICH)/World Health Organization (WHO) Good Clinical Practice (GCP) standards. This provides a unified standard for the European Union, Japan, and the United States, as well as for Australia, Canada, the Nordic countries, and WHO. Thus, any country that adopts this guideline technically follows this same standard. The ICH is a unique project that brings together the regulatory authorities of Europe, Japan, and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.

The purpose is to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. The objectives of such harmonization are a more economical use of human, animal, and material resources and the elimination of unnecessary delay in the global development and availability of new medicines while maintaining safeguards on quality, safety, and efficacy, and regulatory obligations to protect public health. This mission is embodied in the Terms of Reference of ICH.

Specifically pertaining to contract research organizations (CROs) providing clinical-trials services, the ICH-GCP (E6 1.20) defines a *CRO* as "A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions." Furthermore, it states:

- (5.2.1) A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The CRO should implement quality assurance and quality control.
- (5.2.2) Any trial-related duty and function that is transferred to and assumed by a CRO should be specified in writing.
- (5.2.3) Any trial-related duties and functions not specifically transferred to and assumed by a CRO are retained by the sponsor.
- (5.2.4) All references to a sponsor in this guideline also apply to a CRO to the extent that a CRO has assumed the trial-related duties and functions of a sponsor.

**Not a complete literature review*