**Section 250.130 Administration by the Department**

a) Interpretation of Regulations

Nothing in this Part shall be interpreted or used to impose any method of treatment or care inconsistent with the creed or moral tenets of any religious denomination, provided that the requirements as to personnel, building, equipment, space, sanitation, food service, supplies, records, and fire safety are met.

b) Research Programs and/or Experimental Procedures

1) Definitions

A) Experimental procedures − means the use of medical, surgical, manipulative, or psychiatric procedures, drugs, or devices for purposes of diagnosis or treatment of human subjects who are inpatients or outpatients of a hospital and who are subjects at risk.

B) Research program − means any organized activity intended to establish new medical or scientific information, involving medical, surgical, manipulative, or psychiatric diagnosis or treatment of human subjects who are inpatients or outpatients of a hospital and who are subjects at risk.

C) Subject at risk − means any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity that significantly departs from the application of those established and accepted methods necessary to meet the individual's needs, or that increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service. (See 45 CFR 46.103(b).)

2) Entitlement to Conduct Research Programs and/or Experimental Procedures. A licensed hospital may conduct research programs and/or experimental procedures if the hospital meets any of the following:

A) The hospital is formally affiliated with, or is part of, a school whose graduates are eligible for examination for licensing pursuant to statutes, rules and regulations administered by the Department of Financial and Professional Regulation and whose graduates, if licensed, are eligible for admission to the medical staff, provided that the research programs and/or experimental procedures are conducted on a service or within a department of the hospital that is within the scope of the formal affiliation. Documentation of that affiliation shall be available for inspection by the Department upon reasonable request.

B) The hospital is conducting, or proposing to conduct, programs subject to the provisions of 45 CFR 46.101, or pursuant to the provisions of Title 21, Code of Federal Regulations. Documentation of approval of the Secretary of the Department of Health and Human Services for these research programs and/or experimental procedures shall be available for inspection by the Department upon reasonable request.

C) The hospital has an Institutional Review Committee and has complied with all requirements specified in subsection (b)(4).

3) Approval to Conduct Research Programs and/or Experimental Procedures

A) Hospitals that meet the requirements of subsection (b)(2)(A) or (b)(2)(B) may conduct approved research programs.

B) Hospitals that do not meet the requirements of subsection (b)(2)(A) or (b)(2)(B) shall have an Institutional Review Committee as described in subsection (b)(4).

4) Use of Institutional Review Committee to Approve Research Programs and/or Experimental Procedures

A) The Committee shall be composed of not fewer than five persons with varying backgrounds to assure complete and adequate review of activities commonly conducted by the institution. The Committee shall be sufficiently qualified through the maturity, experience, and expertise of its members and the diversity of its membership to ensure respect for its advice and counsel for safeguarding the rights and welfare of human subjects.

B) In addition to possessing the professional competence necessary to review specific activities, the Committee shall be able to ascertain the acceptability of applications and proposals in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, and community attitudes. The Committee shall therefore include persons whose concerns are in these areas. No member of a Committee shall be involved in either the initial or continuing review of an activity in which the member has a conflicting interest, except to provide information requested by the Committee. No Committee shall consist entirely of persons who are officers, employees, or agents of, or are otherwise associated with, the institution, apart from their membership on the Committee. No Committee shall consist entirely of members of a single professional group. The quorum of the Committee shall be defined, but shall not be less than a majority of the total membership, duly convened to carry out the Committee's responsibilities.

C) The Institutional Review Committee shall develop a set of implementation guidelines, including identification of the Committee and a written description of its review procedures. At a minimum, the review procedures shall provide for informed consent, which shall include provision to the individual of an explanation of any procedures that are experimental, a description of any discomforts and risks to be expected, alternative procedures that might be advantageous, answers to any inquiries concerning the procedures, and the opportunity to withdraw the individuals consent and discontinue in the project at any time without prejudice.

D) The Institutional Review Committee shall review all applications for research programs and/or experimental procedures within a hospital and prepare a written report, following the implementation requirements in subsection (b)(4)(C), to be given to the applicant on the acceptance or rejection of the program. A copy of this report shall also be sent to the Department within 30 days after completion of the written report. In addition, minutes covering all activities shall be prepared and made available to the Department. Complete copies of the minutes and reports shall be presented to the hospital's governing authority. Records shall be retained for three years.

E) If the Department finds that the public interest, safety or welfare requires emergency action, the Director, after appropriate medical consultation and guidance, may issue to the applicant a notice not to proceed with or continue (if initiated) the research program and/or experimental procedure that is the subject of the application. The Director shall then obtain further information and clarification regarding the research program and/or experimental procedure that is the subject of the application and make a final decision to approve or to disapprove the identified program and/or procedure.

F) Failure to establish an Institutional Review Committee and/or failure to utilize the Institutional Review Committee shall be considered a violation of the Hospital Licensing Act.

c) Inspections

1) All hospitals to which these requirements apply shall be subject to inspection by the Department, or by such other persons, including full-time local health officers, as the Department may designate. The licensee or person representing the licensee in the hospital shall provide the representative of the Department with any requested hospital records, assist in inspecting the premises, and secure information required by the Act or this Part.

2) The Department shall make or cause to be made such inspections and investigations as it deems necessary*, except that, subject to appropriation, the Department shall investigate every allegation of abuse of a patient received by the Department.* (Section 9 of the Act)

3) Hospitals are authorized to submit a copy of The Joint Commission on Accreditation of Healthcare Organizations' (TJC), or Accreditation for Health Care (ACHC), or DNV-Healthcare (DNV) survey report, certification and accreditation, interim self-evaluation report and Plan of Correction to the Department.

4) Information contained in reports of surveys made by TJC, ACHC or DNV and information gained from reports of surveys or transmittals of information from the various Divisions of the Department or other State agencies may be used in determining the need for inspections for compliance with licensing requirements. All reports provided to the Department for this purpose shall be considered confidential information as provided in Section 9 of the Act.

d) Required Regulations

Hospitals participating in the Medicare/Medicaid Programs shall comply with the regulations of the Federal Department of Health and Human Services as set forth in the Conditions of Participation for Hospitals (42 CFR 482).

(Source: Amended at 46 Ill. Reg. 15597, effective September 1, 2022)