

JCAHO – Ethics, Rights, and Responsibilities

Standard RI.2.180

The hospital protects research subjects and respects their rights during research, investigation, and clinical trials involving human subjects.

Rationale for RI.2.180

A hospital that conducts research, investigations, or clinical trials involving human subjects knows that its first responsibility is to the health and well being of the research subjects. To protect and respect the research subjects' rights, the hospital reviews all research protocols. If another Institution's Review Board (IRB) reviews the research protocols, the hospital does not need to perform this activity.

Elements of Performance for RI.2.180

1. The hospital reviews all research protocols in relation to its mission, values, and other guidelines and weighs the relative risks and benefits to the research subjects.
2. The hospital provides patients who are potential subjects in research, investigation, and clinical trials with adequate information* to participate or refuse to participate in research.
3. Patients are informed that refusing to participate or discontinuing participation at any time will not compromise their access to care, treatment, and services not related to the research.
4. Consent forms address the above elements of performance; indicate the name of the person who provided the information and the date the form was signed; and address the participant's right to privacy, confidentiality, and safety.
5. Subjects are told the extent to which their personally identifiable private information will be held in confidence.
6. All information given to subjects is in the medical record or research file along with the consent forms.
7. If a research-related injury (that is, physical, psychological, social, financial, or otherwise) occurs, the principal investigator attempts to address any harmful consequences the subject may have experienced as a result of research procedures.

* **Adequate information** includes an explanation of the purpose of the research and expected duration of the subject's participation; a description of expected benefits, potential discomforts, and risks; alternative services that might prove advantageous to the individual; and a full explanation of the procedures to be followed.

Excerpt from the *Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Comprehensive Accreditation Manual for Hospitals, The Official Handbook, CAMH Refreshed Core, January 2007*