Clinical research and ethics

Title 45 (Code of Federal Regulations; Part 45), August 1981, requires that all federally supported medical research involving human subjects must pass review by a local Institutional Review Board (IRB). It is to be composed of "at least five members with varying backgrounds . . . and shall include at least one member whose primary concerns are in nonscientific areas; for example, lawyers, ethicists, members of the clergy . . . (and persons with the) competence to review specific research activities . . . to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice." The specific charge of these committees is to "protect . . . the rights and welfare of human subjects of research conducted at or sponsored by the institution." As the charge indicates, the review board must be concerned with the legal and ethical aspects of any research protocol.

Peer review of clinical and research protocols has been standard practice at The Cleveland Clinic Foundation for many years. When Title 45 was passed, the Clinic already possessed a mechanism for formally meeting such a requirement. In January 1980, the Board of Governors invited the author to serve as a consultant to the Clinical Research Projects Committee (CRP) and granted full voting membership in June of 1980. Although the structure of the CRP has changed (it is now called the Research Projects Committee or RPC) and the scientific review of protocols is done at another level, the IRB responsibility is still met by a smaller committee of which the author is a member.

To encourage research while protecting the rights of human subjects, the IRB studies the following issues: (1) scientific merit of the protocol; (2) soundness of the methodology; (3) adequacy of hardware and software; (4) competence of the investigators; and (5) identification and implementation of the ethical aspects of the protocols. The IRB obtains information regarding questions 1 through 4 from the report of the RPC scientific study section's opinion of the methodology and scientific merit of the proposal, and the opinions of the clinicians and researchers on the IRB.

Most ethical problems center around three questions: (1) Are the potential risks to the patient/subject adequately balanced against the anticipated gains either to the patient/subject personally, to future patients, or to the fund of scientific data? (2) Is the financial burden of the research carried fairly by the patient/subject, the institution, manufacturers, or third party carriers? (3) Does the protocol clearly explain the procedures, demands on the patient/subject, and the risk/benefits so that the patient is truly informed and able to consent freely?

The committee then considers the following ethical imperatives: (1) *Freedom* of patient/subjects to direct their lives without coercion and an equal measure of freedom to investigators to pursue significant scientific questions without interference. (2) *Beneficence*: protocols should benefit the patient/subject and/or society. (3) *Nonmaleficence*: the procedures must not place the patient/subject at risk of physical, social, psychological, or spiritual harm. (4) *Justice*: the patient shall not be financially ruined by the procedure. (5) *Confidentiality*: no personal information regarding patient/subjects shall be open to public scrutiny.

The needs of science may pose grave ethical difficulties, especially when the subject of the study is a human being. The task of the IRB at the Cleveland Clinic is to ensure that advances in medicine are achieved in a setting of safety, integrity, and concern for the privacy and dignity of our patients.

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