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Invited Article

Ethical issues in clinical research

Clinical research is defined as a systematic investigation in human beings designed to discover or contribute to a body of generalizable knowledge. As clinical research involves human participants, researchers and their teams are legally and ethically obligated to protect them. In clinical practice a physician would be expected to use interventions that have a reasonable expectation of success and are designed solely to enhance the wellbeing of an individual patient. As against this, clinical research is designed to test a hypothesis, permit conclusions to be drawn, and thereby develop or contribute to generalizable knowledge – here the participant therefore may not get the best known treatment and therefore the obligations on the researcher are more.

The Declaration of Helsinki (available at http://www.wma.net/e/policy/b3.htm) which forms the basis of clinical research today was first accepted by the 18th World Medical Assembly in 1964 and has been revised five times since and the latest version was published in 2000 at the 52nd WMA, Edinburgh, Scotland. It contains 32 principles and has made informed consent a central requirement for ethical research and clearly mandates that "all protocols must be submitted to an ethics committee for review, which must be independent of the investigator, the sponsor or any other kind of undue influence".

The Indian Council for Medical Research (ICMR) Ethical Guidelines for Biomedical Research on Human subjects (available at http://icmr.nic.in/ethical.pdf) was published in 2000 and currently, it is expected that all institutions in India which carry out any form of biomedical research involving human beings should follow these guidelines in letter and spirit to protect the safety and wellbeing of all research participants.

Thus, the two principle protections offered to an individual taking part in any clinical research are written informed consent and ethics committee review. Often a question is asked – which type of research needs ethics review. Clearly all and any research in humans must be preceded by permission from an ethics committee. The type of research could be prospective or retrospective, could be an invasive, experimental study involving a new drug or new device (or even an old drug or device) or a "simple" questionnaire-based study, in normal subjects or in patients, a study looking at histopathology specimen or serum samples, a company-sponsored project or a Government-sponsored one, an academic project or a student's thesis. As long as it involves research on human beings, the investigator must obtain ethics committee permission. If we want research to be internationally acceptable, papers have to conform to these national and international guidelines.

Ethics is the application of values and moral rules to human activities and bioethics is a part of applied ethics that uses ethical principles and decision-making to solve actual or anticipated dilemmas in medicine and biology. There can very few arguments against the need for ethical review of protocols for human research before starting the research.[1]

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REFERENCE

1. Thatte UM. Do all projects require ethics committee clearance? J Postgrad Med 2002;48:91.

With large numbers of original papers coming from our country we will have mandatory 'Ethics Committee' clearance from all authors in the forthcoming issues. This piece is meant to be a guide to investigators for accessing further resources.

Editor