

ETHICS IN CLINICAL TRIALS.

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India has a well written ethical guidelines for clinical trials in human beings drafted by the Indian Council of Medical Research's (ICMR). Still, many trials violate the ICMR ethical guidelines for biomedical research and the World Medical Association (WMA) Declaration of Helsinki: Ethical principles for medical research involving human subjects. The Drugs Controller General of India (DCGI) does not require placebo-controlled trials before granting a drug marketing approval. However, the DCGI does not ban the use of placebo-controlled trials. The ruling on whether a trial design violates ethical principles is left to individual local ethics committees. A trial refused permission by an ethics committee at one trial site may be submitted to another and approved.

According to the journal articles reporting these trials, they were conducted after receiving clearance from the local ethics committees. The existing regulatory apparatus therefore permits unethical trials of no benefit to Indians. There is no evidence that government policy permitting such unethical trials will change in the future; on the contrary, the government priority is, apparently, to ensure that clinical research in India produces good quality data according to Good Clinical Practice standards. Ethical guidelines – including its own ethical guidelines – seem to be of secondary importance.

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