IS YOUR CLINICAL RESEARCH ETHICAL?

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What makes clinical research ethical? What are the ethics of clinical research? Is your clinical research ethical? The institutional Ethical Review Boards (IRB) and ethics committees look at these questions and based on ethical considerations of your research proposal, either approve, recommend amendments, or reject your research proposal.

The primary objective of any clinical research is to ultimately improve human health through generation of new knowledge that could be applied to human beings at large. The research participants are exposed to the potential harmful effects of the experimental diagnostic tools, pharmaceutical agents, implants, or other agents. Due attention must therefore be paid to the well-being of the participants who volunteer in order to advance our knowledge by exposing themselves to such risks and harmful effects.

There are several examples in the history of clinical research where safety of the participants was neglected. In fact, several studies, including the Tuskegee Syphilis study, the Nazi medical experimentations, the Willowbrook State School study, and many others were outrightly against the basic human rights, unlawful and unethical, to say the least. These studies mainly exposed uninformed and unaware individuals to diseases or subjected them to unproven treatments. As an aftermath of these and similar studies and to prevent violations of basic human rights and ethical principles, the need for rules & regulations governing human research became evident.

The Nuremberg Code, the Declaration of Helsinki, the International Council on Harmonization–Good Clinical Practice (ICH-GCP) guidelines and all other codes, declarations and guidelines have attempted to design and develop ethical guidelines to protect the research participants during the planning, implementation and follow- up of clinical research studies[1-3]. All these guidelines emphasize upon voluntary participation, informed consent, respect, beneficence, minimized risk, and independent review during the planning and implementation of research projects.

With this background, the title question remains the same: Is your clinical research ethical? If your research is as per principles of these guidelines? Emanuel et al in their commentary on what makes research ethical have summarized the above mentioned and other guidelines and discussed seven requirements that determine whether your research is ethical [4]. These requirements are: (1) social and scientific value of research, (2) validity of the method (3) fair subject selection, (4) favorable risk-benefit ratio, (5) independent review, (6) informed consent, and (7) respect for enrolled and potential participants.

To be ethical, your research should carry social and / or scientific value by contributing to the understanding of health, prevention, diagnosis, and treatment of diseases to justify exposing humans to the risks and inconveniences of clinical research. Answer to the research question should be sought using rigorous and correct research methodology. Representative subjects should be selected after seeking informed consent, keeping in mind the risks and benefits of participating in the research. An independent review board or committee should look into all aspects of the research, identifying and addressing all ethical issues. From the moment they are recruited until their involvement is complete, all prospective and enrolled research participants should be treated with respect. This would entail monitoring their welfare and notifying them of the research's findings, as well as respecting their right to privacy, change of mind, and withdrawal from the study. If your research proposal takes care of the above, go ahead, it is ethical. If not, re-think and re-plan before taking any other steps.

CAPSULE SUMMARY

When clinical research prioritises participants' well-being, receives informed consent, maintains a favourable risk-benefit balance, and employs rigorous scientific procedures, it is considered ethical. Independent review boards verify that ethical rules are being followed. Researchers must respect the rights and privacy of participants, and their studies must have scientific or societal value.

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