Trends in Clinical Research: Open Access

Trends Clin Res, Volume 1, Issue 1
http://crescopublications.org/pdf/TCROA/TCROA -1-R003.pdf
Article Number: TCROA -1-R003

Short Communication Open Access

Understanding Patients Perspective on Clinical Research in Indian Population

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The survey reflects that professionals in clinical research are aware of the ethical issues of clinical research in India. In spite of varied perceptions, the main areas of concern appear to be informed consent process and documentation, empowerment of ECs based on independency and competency, and patient awareness about safety and compensation rights.The survey participants identified several reasons why lay person is unable to participate effectively in EC proceedings. The opinion on adequacy of safety review by EC was divided. However, several useful suggestions were made to improve the safety review process e.g. EC audit, separate committee for safety review, limiting number of trials reviewed by EC and face-to-face meeting with study team. The respondents recommended several areas for trainings of EC members such as GCP, regulations, SOPs, and consent process, with a stress on ethical thinking.

The regulatory process appeared adequate to majority of respondents. However, there were suggestions to improve the process e.g. trained GCP experts to inspect/monitor trials, clarity in guidelines, and regulatory bodies meeting the subjects.Majority participants felt that during the informed consent process: a) alternative treatment modalities are explained and choice given to subject; b) subject is offered the opportunity to ask questions; c) participant rights are explained to subject/legally acceptable representative; and d) patients are able to refuse participation in clinical research. As the majority of survey participants were from industries, who are not involved directly in the consent process, these perceptions require confirmation by survey of investigators, ECs and trial participants.

About three fourths of the responders felt that low literacy levels increased the vulnerability levels for patients and suggested measures for its mitigation e.g. EC oversight for consent process, creation of patient support groups, role of media in creating awareness about clinical research.A large majority favored compensation for trial subjects for trial related injury, and felt that multiple stakeholders could collectively decide the compensation. Majority of participants favored the use of placebo with adequate safeguards to protect the trial participants. Post-trial access to investigational drug was acceptable to a majority.

The main limiting aspect of this survey is a small sample size. Besides, majority (79.4%) of respondents are from industry. A large survey with adequate representation of all stakeholders-investigators, EC members, media, and patient groups is required to validate the survey findings. The use of placebo was justified, subject to the condition that: a) the said disease had no defined/established standard of care; b) adequate rescue procedures for patient withdrawal and safety management were ensured; c) back-up investigators present at the site for additional oversight; and d) additional monitoring ensured by the sponsor/CRO. It was also opined that the EC should review the scientific soundness of the placebo-controlled trial in greater depth and have an increased level of subject education at screening stage.

Other miscellaneous opinions suggested that standard treatment must also be provided along with the placebo since putting the patient only on placebo would be unethical; also, wherever possible, patient should be in-patient so that emergency medical care could be made available; and placebo should be used only for proof of concept trials.