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## Perception about clinical trials/clinical research among people in Indian subcontinent

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**Statement of the Problem:** Clinical Research (CR) in developing countries, sponsored by developed countries has been under the lens since few years. However, hardly any empirical studies have been conducted on ethical issues in India. Hence limited knowledge is available to the public regarding the guidelines, ethical conduct, and also the ethical issues involved in clinical trials in India.

**The Purpose of this Study:** Considering the recent criticism on CR scenario in India, to encourage clinical trial participation, every individual should be entitled to complete information about the trial before involvement and about the outcome on completion. The purpose of this study is to explore and understand the perception, and understanding of clinical research amongst that population of India who are fit to directly or indirectly participate in CR.

**Methodology & Theoretical Orientation:** This ethics committee approved pan-India multi-strata study used multivariate questionnaire-based survey among 8416 individuals selected with snowball sampling; the participant population consisted of three groups: potential trial patients, parents of minor subjects, and healthy volunteers.

**Findings:** The study revealed lack of awareness in multiple parameters of clinical research among participants. Moderate awareness on questions of clinical trials benefit to society (67%) or new drug development (57.5%); face direct challenge from lack of knowledge (30% of the participants) about subject rights & safety measures taken by government regulatory authorities. Almost 58% of subjects were unaware of the amendments of guidelines regarding adequate compensation in case of adverse outcomes.

**Conclusion & Significance:** Ethical and scientific benefits are always intertwined in clinical research involving humans. Effective collaboration of ethics committee and sponsor's team should be practiced to regain public faith and better conduct of trials. The study results call for initiatives like organizing trial summits involving patients, NGOs, sponsor's representatives, apart from other stakeholders.

### Recent Publications

1. Kaushal Kapadia (2015) Understanding patients perspective on clinical research in Indian population. South American Journal of Clinical Research 2(1):110-121.
2. Kaushal Kapadia (2015) Understanding clinical trial participants (healthy volunteer) perspective on clinical research in Indian population. South American Journal of Clinical Research, 2(2):44-49.
3. Kaushal Kapadia and Deven Parmar (2016) Understanding participants (parents, in case of pediatric participation) perspective on clinical research in Indian population. Research Chronicle in Health Sciences 2(1):255-259.
4. Kaushal Kapadia (2016) Perspective on clinical research India (Ed. 1), Lambert Academic Publishing (ISBN: 978-3-659-95568-6).

### Biography

Kaushal Kapadia is an expert clinical research professional with an experience of more than 10 years in clinical research operations. Apart from that an author for the book titled "*Perspective on Clinical Research, India*" also a best poster award winner at an international conference organized by OMICS in the year 2015 organized in Florida, USA.

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