

## Research Ethics in Developing Countries: Issues, Opportunities and Challenges

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Research is necessary for progress and mandatory for the success of any nation. With the advancement in science and technology in today's world, maintaining highest ethical standards in research is becoming a challenging task and increases responsibilities of investigators.<sup>1</sup> Protection of human subject's rights is of paramount importance in conducting any research involving human beings.<sup>2</sup>

Research on human subjects is becoming increasingly challenging in developed world as research subjects are more aware of their rights and less willing to participate unless well compensated. This has made research on human subjects in developed world very expensive and investigators/industry and research sponsors are increasingly looking towards the developing world to conduct research as it is less expensive. This has resulted in very serious concerns being raised by various stakeholders to ensure the rights of human subjects are protected.<sup>3</sup>

Research subjects in the developing world are a vulnerable population and require additional safeguards for protection of their rights. Research subjects in the developing countries are not very much educated and therefore it is important that written Informed Consent form administration is properly conducted. It should be in simple and preferably local language.<sup>4</sup> The argument that less educated research subjects cannot be made to understand research details is not true. Every effort should be made that the research subject understands the nature of the research project, the risks involved and benefits offered if any. The right to participate or not to participate should be clearly written and made clear to the research subject. The approval of written Informed Consent form by Institutional Review Board (IRB) or Ethical Research Committee (ERC) should be mandatory to ensure it guarantees research subjects rights. Signature of a witness not from the research team should be taken to ensure research subject protection.

Financial incentives to relatively poor research subjects from the developing countries can compromise their rights and safety.<sup>3</sup> It should be the responsibility of ERC to ensure

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that those with limited financial standing are not exploited and lured into taking risks without their clear understanding and appropriate compensation/insurance. Conducting human subject research in developing countries can be an incentive for Investigators as clinical drug trials can be done at a lower costs compared to those conducted in the developed countries.

At one end there are issues of safety of research subjects due to their vulnerability and on the other hand there are opportunities of bringing in research into the developing countries that has its own advantages. Research happening in the developing countries leads to capacity building<sup>5</sup> in research of local human resource and they also get the opportunity to get on to the map of research activities going on around the globe. It brings in training opportunity for human resource in research in these countries and also enhances their earning capacity at an individual/institutional level. Researchers from these countries can learn from experience and training opportunities available in the developed countries as a result of research collaboration.<sup>6</sup> Developing countries are therefore able to enhance their revenue generation as a result of research activities.

There are issues with regards to infrastructure and human resource availability for the conduct of human subject research of high quality in developing countries. Infrastructure is lacking altogether or is of poor quality hindering quality human subject research. Funds are required to invest in infrastructure development and maintenance in developing countries. Human resource with proper training, certification and experience to conduct high quality human subject research is lacking. Brain drain with migration of suitably qualified researchers to developed countries prevents whatever human resource exists in developing countries. Consistent government policies in support of promoting and encouraging human subject research are required.

Presence of academia is required to provide the necessary expertise necessary for human subject research in developing countries. One of the most important prerequisite for ensuring human subject research rights and safety is the establishment and presence of IRBs or ERCs at level of various academic or research institutions. Such IRBs should comprise of individuals who are suitably qualified and experienced to address ethical issues and safety of human research subjects. Such boards should have individuals from varied backgrounds including law, social sciences and religion in addition to medical and nursing. Members of IRBs should be of proven credibility and should not participate in the discussions concerning research protocols where they may have conflict of interest.

Standard of care given to a research subject in human subject research carried out in developing countries has been a matter of grave concern. Researchers should provide the best available care to the research subjects according to some while others argue that it should be the best available care in the research settings. This subject has been open to discussion and debate.

Collaboration between institutions/individuals from developed and developing countries is the way forward but should be done in a manner that is ethical and drives on the strengths of all stakeholders and results in mutually beneficial<sup>7</sup> outcome for all involved. Developed countries offer the necessary human resource and necessary finance whereas developing countries offer availability of large human subject research opportunities. If interests of all concerned are taken into account in an ethical and mutually beneficial manner in the sharing and distribution of these resources and outcomes of research than it will result in a productive and long lasting relationship between these stakeholders.

In conclusion, research in developing countries should be collaborative, ethically sound and mutually supportive. It should protect human subjects and they should be adequately compensated for their participation.

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