e-ISSN: 2319-9865
p-ISSN: 2322 -0104

Research and Reviews: Journal of Medical and Health Sciences

# Ethical Obligations of the Trials in Developing Countries

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Editorial Article

Received: 12/05/2015
Revised: 18/05/2015
Accepted: 10/05/2015

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Keywords: Clinical trials, ICHGCP, CDISC, Adverse Drug

## Introduction

Many developing county [1] trials are being funded by developed countries, but the major problem concerning with these trials are ethical issues[2-22] as the inequalities in resources in devolving countries pose a real risk in exploiting the context of sponsored research [23,24]. The difference in the motives of the research between sponsor and sponsored countries mainly in the area of national priorities of the provision should be set as per the sponsored country [2,5]. This is because when a trial is funded, which is outside the national priority, the ethics committees must justify the relevance of the outcomes. There is lot depending on the ability of developing country to verify the relevance of the research with their needs [25-31].

There are many concerns issued by developed countries on the trials funded to developing countries the major ones are 1) Standards of research in developing countries and 2) a proper informed consent.

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## Standards of research in developing countries

Clinical trials conducted by developing countries in developed countries have become controversial over last decade, this is because developing countries are at major risk of diseases due to their standard of living, Regional and cultural aspects, backward communities, etc [32-38]. with more scope of research but the standard of research dint prove to be worthy for many research funding's when comparing the studies with the other studies done in developed countries over the years. Wendler D, et al. [24] concluded that "commentators argue that subjects must receive the best methods available worldwide. Others worry that this requirement may block important research intended to improve health care, especially in developing countries".

For this he proposed a, framework for the conditions under which it is acceptable to provide subjects with less than the best methods. Specifically, institutional review boards should assume a

default of requiring the "worldwide best" methods, meaning the best methods available anywhere in the world, in all cases [39-45].

However, institutional review boards should be willing to grant exceptions to this default for research studies that satisfy the following 4 conditions: (1) scientific necessity, (2) relevance for the host community, (3) sufficient host community benefit, and (4) subject and host community no maleficence.

## Proper Informed Consent

Proper informed consent is a major issue reviewed by the Institutional Review Boards, because it is a vital document in the Trial process and is important factor in doctor patient relationship in the Trial process. Informed consent usually is an ethical concept—where the patients or participants should understand and agree to the potential consequences of the drug or intervention. There are many laws and clause that talk about informed consent, but there were changes in laws over the period of time. These informed consents change from region to region and state to state, this is the area where the developed nations raise their concerns in regards to the funding because of the variation in the trial process which leads to differences in the trial outcome [46-56].

Many developing countries are the backbone for numerous trials as their population is at major risk to diseases; this had been taken as an advantage in the past where many malpractices in the trial process were done which include mainly: Trials without proper informed consent were conducted which resulted in the death of many participants over the years. Illiteracy in developing countries was the major reason for this, people were considered as trial subjects without their knowledge or information in many of the trials [57-61]. Such incidents were common in the past but know the new rules developed by IRB are asked developed nations to be strictly followed. These new rules include e-informed consent which is an electronic way of informed consent where the total process of the informed consent is to be recorded and sent the review boards [62].

## Conclusion

There should be a standard way for trials conducted in developing countries as they have to get the funding for the trials process from developed countries.

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