

Biomedical Research Involving Human Participants in India - Some Observations

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ABSTRACT

Published on 28th March 2011

Biomedical research involving human participants is an area of concern world over and once in a while catches media attention when some sensational exigencies related to research occur. These issues could be either adverse events following research or violation of ethical principles. This may either follow “whistle blowing” from some quarters or when instances of exploitation of underprivileged are brought to light by activist groups or watchdogs.

Under this principle it is mandated that “due care and caution must be exercised at all stages of research and experiments to ensure that the research participant and those affected by it including community are put to the minimum risk, suffer from no known adverse effects, and generally, benefit from and by the research or experiment and that requisite steps are taken to ensure that both professional and ethical reviews of the research are undertaken at appropriate stages so that further and specific guidelines are laid down, and necessary directions given, in respect of the conduct of the research or experiment”. This has led to the constitution of Institutional Ethical Committees.

Keywords: Biomedical Research, Institutional Ethical Committee, Consent.

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INTRODUCTION

Biomedical research involving human participants is an area of concern world over and once in a while catches media attention when some sensational exigencies related to research occur. These issues could be either adverse events following research or violation of ethical principles. This may either follow “whistle blowing” from some quarters or when instances of exploitation of underprivileged are brought to light by activist groups or watchdogs. The latest in this series is the vaccine trial on HPV infection conducted in the poor and underprivileged without their knowledge and consent.

Even though the institutional mechanisms for ensuring safety of “researched as well the researching” are well laid down and even enacted, they still remain in paper only in many parts of the developing world. Unfortunately India is no exception. Kerala, the southernmost part of Indian peninsula, well hailed for its high health achievements and health activism is also a hotspot for biomedical research involving human participants and the development of several hi-tec healthcare institutions over the past two decades has also opened up newer vistas for biomedical research. Some salient observations and anecdotes related to biomedical

research involving human participants in Kerala are being discussed in brief in this commentary.

Institutional Mechanisms for ensuring proper conduct of research

Under the statement of general principles in the “Ethical guidelines for biomedical research on human participants” released by the Indian Council of Biomedical Research (ICMR) in 2006, the fifth item relates to precaution and risk minimization.

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It was with this principle in mind that the Institute Ethics Committees (IECs) were proposed and mandated in the guidelines. All institutions where such research is being undertaken are mandated to have duly constituted IECs to oversee the overall conduct of research. One grievance raised by researchers was the lack of institutional mechanisms for reviewing their protocols as many institutions did not have IECs which hampered research in such institutions. Reasons cited for the lack of IECs ranged from the simple apathy on the part of the authorities of the institutions in setting up such bodies to the inability of small institutions for creating such bodies. The latter reason often is compounded by the fact that smaller institutions might neither be able to get sufficient number of experts and technical professionals to run such bodies nor are able to afford them in terms of their maintenance cost. It is to be noted in this context that one of the noteworthy changes that have occurred in the area of biomedical research during the period between the ICMR guidelines of 2002 and 2006 is the emergence of entities called “Independent Ethics Committees {IEC (Ind)}”. These bodies are expected to be the answer to the grievances raised by the foresaid researchers. Unfortunately, independent ethics committees are yet to find their places in Kerala.

Overall ethics awareness of research community in Kerala

Several reputed research institutions are functioning in Kerala and some among them are equally involved in clinical care as well. Some of them have duly constituted IECs and some others do not have any. However, this could be considered as a general phenomenon in the developing world where the ethics review mechanisms are not as robust as they are expected to be.² Even in those institutions where the IECs are functioning neither the IEC members nor the researchers get any chance to be updated regarding the ethical implications of research. In some institutions the responsibility of IECs is largely confined to the initial review of protocols and ‘approval’ and the rest is left to the researchers. Nowadays, publishing in peer reviewed journals have become more and more stringent and almost all of them insist on having the proposals approved by the IECs. Thus the IECs have become an ‘unavoidable evil’ and many institutions constitute IECs only because of this pressure. Even though ICMR has taken up some initiatives to create ethics awareness among researchers, ethics teaching never figures as a mainstream agenda in our medical schools and even research organizations. It could even be found that

researchers involved in biomedical research have never put their hands on the guidelines issued by the ICMR. This is a very serious state of affairs.

Case of “Physician Researchers”

In research institutions where healthcare is also being provided and vice versa, the physician or the researcher assumes a dual role. The researchers are the healthcare providers as well and the ‘researched’ are the healthcare seeking patients.

Instances of exploitation had been reported from several parts of the world where physicians also wear the mantle of researchers and patients were being unknowingly driven to the murky areas of shady research by the physician-researchers. They date back to the II World War days and the experiments on war victims by Nazi doctors. There are anecdotal evidences to believe that research is taking place in several institutions without even the knowledge of the researched. The process of ‘informed consent’ is limited to getting a signature in a printed format by some of the ‘public relations staff’ and the patients might never know whether the consent was for treatment or for research. In some instances, the researchers make the patients believe that they were providing very costly treatment free of charge wherein actually they are the research molecules directly being tested in patients. When it comes of specialist care, the physician may even go to the extent of ‘physician paternalism’ and the power relations often force the patients to accept the ‘test medicines’, even though they were not fully aware of the risks and benefits and their acceptability might have been doubtful had they been provided full information and freedom to choose the interventions voluntarily. Instances had been reported from other parts of India where the researchers were found to be accepting incentives and favours from pharma companies for recruiting patients for such research.³ This aspect needs detailed investigations in Kerala also where research might be progressing at least in some institutions in the guise of healthcare.

Case of “indigenous medicines and research results being published as advertisements in lay press”

Though not fully approved for various reasons, one accepted norm is that unscientific research on itself is unethical. So, the research needs to be scientifically devised and the research methodologies used need to be well accepted and approved by professional peers. Unfortunately, several instances of ‘research’ are being

reported in Kerala, the design and methodology of which are dubious in nature. This is more in the case of indigenous products and interventions. Though the ICMR guidelines are very clear about the research on indigenous products, such guidelines are often flouted and instances of blatant violation of such guidelines are occurring very often. Hundreds of new products in catchy names are being launched regularly claiming that they were all research products from Ayurvedic texts and scriptures. Qualifications of researchers and the methodologies employed are never disclosed. The claims are never substantiated by evidence in the form of publications and publishing, if at all done, is in the lay press. Even this publishing in the lay press is often as paid advertisements and the clients are made believe that the products are all research outcomes. A recent newspaper report claimed that a product was tested for its 'blood sugar lowering effect' in a certain number of patients and was released as a remedy for Type 2 Diabetes in one of the leading dailies in Kerala. Any number of such 'research' reports appears frequently and there exist no mechanism either to check this menace or to book the 'culprits'.

Dilemma of genuine researchers

Lack of IECs in their institutions is an important dilemma to any researcher and till recently there was no other alternative other than submitting their protocols to ICMR for review. An ordinary researcher might not have that sort of time or exposure to go for all these formalities with the result that the research itself often gets dropped. However, the emergence of Independent Ethics Committees {IEC (Ind)} was expected to solve some of these issues. But these Ethics Committees have not found their place in all parts of the country and their authenticity and genuineness are yet to be impressed upon the research community and the academia.

Since, the review in these bodies are being undertaken on a 'paid basis', the conflict of interest issues always loom large and it becomes imperative to prove their genuineness and the onus fall on them only. It is hoped that these bodies may emerge as a robust mechanism to redress the grievances of researchers whose institutions lack IECs.

Way forward

We have to accept with grace the fact the ethics awareness among our biomedical researchers is not to the level desired in several instances and conscious efforts need to be undertaken to create such awareness. Ethics education needs to be made emphatic in medical curriculum and ethical guidelines for conducting research on human participants need to be disseminated widely to create better awareness about them and for better adherence to such guidelines while conducting research. All institutions where research involving human participants is being conducted should try to establish IECs in them. Since the IEC (Ind) s are yet to get established in all parts of the country, organizations like Indian Medical Association may take a lead role to establish Research Ethics Committees so that their members could submit research protocols for review. Such associations are to take a lead role in ensuring ethical biomedical research in the country.

END NOTE

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Conflict of Interest: None declared

Cite this article as: V Mohanan Nair. Biomedical Research Involving Human Participants in India - Some Observations. Kerala Medical Journal. 2011 Mar 28;4(1):19-21

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