EDITORIAL

Ethics committee approval for academic research: is it a workable proposition in developing countries

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ABSTRACT

This editorial aims to draw attention of journal editors and policy makers to a very pertinent question related to publishing. The mandatory requirement of ethics committee (EC) approval is a much needed regulation in light of serious human rights violations in past. However, it may not be always feasible for researchers to comply with this requirement. There is a need to develop some guidelines as to how such instances should be dealt with. This is not a regressive approach. The AP J Psychol Med is very much aware and concerned about the protection of the rights of study participants, and endorses the publication requirements of various organizations.

Key words: Ethics committees; Research

INTRODUCTION

A few years ago, I attended a workshop on research methodology being organized by a medical college in collaboration with an international organization. I was casually interacting with an American delegate, discussing various aspects of research. I asked her whether it is necessary in Western countries to have ethics committee (EC) approval even for academic research (that which is not clinical trials). I was expecting a ‘no’ answer. However, she said it is a mandatory ethical and legal requirement! Then, I enquired regarding the EC fees; do authors need to pay EC fees to get the study approval? She replied that for academic, non-funded, non-commercial research, authors are not required to pay EC fees. However, for clinical trials, EC fees should be paid by the investigator, who in turn gets paid by the study sponsor. She wondered how somebody can expect the investigators engaged in non-funded research to pay the EC fees.

An EC is supposed to review, approve (or disapprove) and monitor the proper conduct of biomedical research involving humans. They need to do a risk-benefit analysis to decide that in the proposed research protocol, the interest of science does not override the interest of the society. [1]

Violation of human rights in research

If we go through the history, there have been numerous instances of major human rights violations and grossly unethical human research. The most notorious examples include, the ‘Nazi experiment’, [2] the ‘Tuskegee syphilis study’, [3] etc. The ‘Tuskegee syphilis study’ (1932), [3] was a 40 year study done by the US Public Health Service in Alabama. The study subjects were 400 poor African American men who were promised free ‘treatment for bad blood’. These subjects were actually suffering from syphilis. The standard treatment for syphilis, i.e., penicillin was withheld, though it was available. The ‘said treatment’ was in fact never given. The subjects were not informed about the risks associated with their participation and their consent was not taken. The study results were later published in medical journals. Heller, in 1972, had exposed the unethical aspects of the study. But, by then many of these subjects either died or suffered from serious syphilis related conditions. This was a blatant disregard of human rights.

Why ECs came into existence

The above mentioned and other ‘notorious studies’ compelled the creation of the Belmont report, [4] which stresses upon the following three fundamental ethical principles for studies involving human subjects:

‘Respect for persons’: protecting the autonomy of all people and treating them with courtesy and respect and allowing for informed consent. Researchers must be truthful and conduct no deception;

Beneficence: The philosophy of “do no harm” while maximizing benefits for the research project and minimizing risks to the research subjects; and

Justice: ensuring reasonable, non-exploitative, and well-considered procedures are administered fairly-the fair distribution of costs and benefits to potential research

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participants-and equally.’

In 1947, the first International Statement on the ethics of medical research using human subjects, i.e. Nuremberg code, [5] mandated that the consent should be voluntary. In 1964, the World Medical Association formulated the Declaration of Helsinki-ethical principles for medical research involving human subjects, [6] which says that ‘the research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins.’

In 1980, the Indian Council of Medical Research (ICMR) released a ‘policy statement on ethical considerations involved in research on human subjects’ for clinical research in India. In 1993, ‘International ethical guidelines for biomedical research involving human subjects’ were released which mandated ‘that all proposals on biomedical research involving human participants should be cleared by an appropriately constituted Institutional Ethics Committee ... ... to safeguard the welfare and the rights of the participants.’ [7]

The Indian Council of Medical Research also describes certain special situations for EC approval, ‘small institutions could form alliance with other IECs or approach registered IEC (ind). Large institutions/Universities with large number of proposals can have more than one suitably constituted IECs for different research areas for which large number of research proposals are submitted......A sub-committee of the main IEC may review proposals submitted by undergraduate or post-graduate students or if necessary, a committee may be separately constituted for the purpose, which will review proposals in the same manner as described above.’ [7]

According to ICMR, [7] the following are the responsibilities of an IEC, ‘1) to protect the dignity, rights and well being of the potential research participants, 2) to ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs, 3) to assist in the development and the education of a research community responsive to local health care requirements.’

DISCUSSION

Fees for consideration of research proposals by EC

The world scenario

In developed countries, most of the research is carried out at institutes that are either funded, or have finances exclusively allocated to take care of EC expenditure. According to the Australian government National Health and Medical Research Council, NHMRC, ‘the decision to adopt a policy for charging fees for access to HREC reviews is largely an administrative decision......organisations and institutions should consider whether the payment of a fee will compromise the integrity of the process of ethical review and the monitoring of approved research......To ensure impartiality, organisations and institutions should keep the processes for collection, administration and use of fees separate from the administration of HREC activities. In addition, implementation of a fees policy should not have the effect of preventing the consideration of research proposals that would otherwise have been considered in the work of the HREC for example, high levels of fees for staff or student research.....’ [8]

The Indian scenario

The scenario is not the same in developing countries, like India. Research is still in infancy in this country. When we talk about doing research here, there is a lot of resistance from the administrators. When we approach authorities requesting for EC approval for non-funded research, we get a reply, “Do you think EC members do not have any other work”? The maximum they do is, to consider approving the study protocol alongside a clinical trial; meaning they would club many approvals in a single sitting. Thus, basically, we the researchers are at the mercy of authorities. In fact, the ICMR does not mandate EC fees; it just says, “Prescribed fee if any, should be remitted along with the application”. [9]

National level institutes

In India, institutes such as NIMHANS, Bangalore; PGI, Chandigarh; etc have enough resources which can meet such demands.

Private institutes and corporate set-ups

The scenario is a little different in private medical colleges and corporate hospitals; and looking at the current trend, more manuscript submissions are from these places. The possible reasons are, i) they have huge funds to allocate money for research and EC approval, ii) they are very particular about Medical Council of India (MCI) regulations, which mandate publications from faculty for appointments and promotions. However, researchers who work in governmental medical colleges and other institutes face a lot of difficulty. There is inertia and resistance from the authorities.

Private clinics/small set-ups

One of the best possible research studies are in fact possible in private set-ups because of the number and variety of patients the private practitioners treat. Most of the clinicians are busy with patients; few spare time for academic work; a few others apart from their clinical and academic responsibilities have inclination to do research. They wish to do studies and publish their research findings. Most of the journals, especially the international ones require the authors to declare that their study has the EC approval. A few of them also want the authors to submit a scanned copy of the same to the journal editorial office.

I am primarily employed in a government institute which has an EC. I am fortunate that at this institute I do not face this problem, because the EC meets regularly and considers students’, faculty’s, and non-funded research free of cost. However, because I am also in private practice, I have a
problem when I wish do studies in a private capacity. A few years back, I submitted a research proposal to an Independent Review Board (IRB) which I wanted to do in my private clinic. With lot of pursuance, the IRB members agreed to take-up the proposal free of cost. I was already seeking approval from this IRB for a clinical trial. This IRB decided to club my academic research proposal along with this clinical trial approval. My clinical trial was approved in one sitting, but the academic protocol was never approved. I had to ultimately drop the idea of going ahead with this academic study proposal.

Where will such private researchers get EC approval from? The maximum they can do is to approach an IRB. Which IRB would be willing to give study approval, more so when authors cannot pay the EC fees, because their study is non-funded? Some of the IRB fees are exorbitant, which researchers cannot afford. I am aware of a few ECs which charge INR 35,000 for approving the study protocol of academic research. The average researcher in India will not be able to afford this kind of money. I did a Google search on July 5, 2014 to know how much were the ECs charging for study approval. The key words used were, ‘ethics committee; fees’. The first hit took me to a site which mentioned about various types of fees structure. No type of research was exempt from payment. However, I was relieved to see the following mention, “A special ethical review fee may be considered, on case to case basis if sponsors and all other stake holders are not-for-profit organizations and data generated shall not be used for any commercial purposes”. Because of confidentiality reasons, I cannot cite this EC.

I agree that EC members are busy people and find it difficult to spare their precious time for a free work. Also, the logistics of EC meetings have to be met. But, then what should private researchers do? I think the scenario may be the same in other parts of the world too. Does this mean that private practitioners cannot do research and publish their study findings, because of the lack of EC/IRB approval?

**CONCLUSIONS**

The issue raised by me in this editorial is extremely important, so I believe! I am not advocating against the need to obtain an EC approval; but, what I am saying is that many times it may not be possible for researchers/authors to obtain EC approval because of the above mentioned reasons. Just because EC approval is not there, it does not mean that the research was not conducted ethically; also, just because a study has EC approval it does not mean that the study was in fact done ethically. “...editors should consider IRB approval as only one indication of the ethical content of a study. It is not sufficient in itself.” [10] There is a need to evolve consensus guidelines. The journal editors should use a discretionary approach in deciding which type of studies need EC approval. Clinical trials and academic research cannot be judged with the same yardstick. Interventional studies are one of the types of studies which should definitely require EC approval. I think this issue of EC approval should not be included as a blanket requirement for doing studies or for publishing ones study findings. This is not a step backward, but a more practical approach. Let us make research interesting and challenging, not something people should be afraid of!

The views expressed in this article are solely of the author. It does not reflect its endorsement by the journal, the editorial board, the publisher, or the society.

The terms ‘Institutional Ethics Committee’ (IEC), ‘Ethics Committee’ (EC) and ‘Independent Review Board’ (IRB) serve the same function.

The AP J Psychol Med is a member of the Committee on Publication Ethics (COPE), The World Association of Medical Editors (WAME), The European Association of Science Editors (EASE) and the International Committee of Medical Journal Editors (ICMJE). The journal confirms to the publication guidelines set forth by these and other national and international organizations.

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**Conflict of Interest**: The author is a member of an IRB in Hyderabad, India. He was a member of Association of Clinical Research Professionals/Academy of Pharmaceutical Investigators and Physicians (ACRP/APPI), USA. He was an ICH/GCP (International Conference on Harmonisation/Good Clinical Practice) trained Certified Physician Investigator (CPI), ACRP/APPI, USA; this certification has expired on 31/05/2012

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