COMMENTARY

Ethical approval for research in developing countries: problems and solutions

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Bipeta, [1] raises highly important issue of ethics committee (EC) approval for research in the context of developing countries. After giving a detailed background of the excesses committed by the apparently well intentioned researchers at the turn of this century, he highlights the need for ethical approval of research involving human subjects. He raises two highly important points as following: 'I am not advocating against the need to obtain an EC approval; but. 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…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.' [1]

While I agree with his argument, my concern is that most of the problems he highlighted are the result of poorly developed mechanisms relating to ethical approval of studies, especially in the developing countries. The investigators from developing countries face greater resource constraints which also includes ethical approval. It is understandable that hurdles posed in ethical approval results in further frustration for a researcher who already has limited time and resources. However, the principles and requirements for ethical approval should be universal.

Bipeta, [1] also highlights the problem of investigator initiated studies with no funding conducted perhaps by an academician working in private practice, with little or no resources which are readily available to an academician working at teaching institute. I will not comment on this further, as I believe this is an issue of feasibility rather than problem in managing ethical approval. While I believe that not all research would require the same procedures for ethical approval for every type of study (see below), the question of ethical approval should not depend upon the resources available to a researcher.

I argued elsewhere that the research is the art of doable. [2] A good research question is always the one, which a researcher *can answer within the available resources*. The required resources, of course, include resources, both human and capital which are necessary for obtaining the suitable approval from an ethics review board. In case those resources are not available to the investigator, then perhaps study is not feasible in first place. In such a situation, the investigator need to revisit the research question and change the design, (or even better do something less demanding, such as a systematic review!). Attempting to answer a question which lies beyond our resources is one of the commonest mistakes which are more likely to be committed by a young enthusiastic researcher and every investigator needs to be aware of this. If this is detected at the ethical approval stage, it will save lot of effort and energy.

The related question is that whether all research requires ethical approval and whether editors should require a letter of approval for all the submitted research. I think this is not an appropriate question to ask. A proper question to ask is whether all research requires the same level of ethical approval. A descriptive study investigating the clinical features and presentation of a disorder based on clinical record should not require same degree of scrutiny for ethical approval, as is required for an interventional study. Few screening questions related to the risk to participants, procedures for securing personal data and consent procedures would indicate whether further scrutiny is required for ethical approval.

This distinction is rarely made in most developing countries where as pointed out by Bipeta, [1] the resources are limited. One size (or rather one stick in case of ethical approval!) fit all is not a proper approach. Non-interventional research particularly those based on patient records or requiring minimal consent for sharing personal information can be screened by committees comprising of one to three members assessing the risks to participants. If the risks are minimal or investigators have given adequate mitigation strategies, then such a research should be approved straightaway. I would think that most of research form developing countries would fall in this category and such a procedure should not be taxing for the investigators. This will also save time and resources for focusing on research which has complex ethical issues and approve these studies in timely manner.

The ethical approval is an intervention to safeguard participants' best interest and minimize the harm. Like any other intervention it must be proportionate, safe (hugely expensive and complicated ethical procedures put patients at risk by preventing useful advances in the field) and cost effective. These criteria should also guide editors in requiring ethical approval for submitted research.

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References

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2. Farooq S. The right question and the research question. J Coll Physicians Surg Pak 2001; 11: 728-9.

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