Review Article

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Investigators viewpoint on ethics, methods, and informed consent in clinical trials

INFORMED CONSENT

This is an essential document that describes the study. However, often is too detailed for a common man to understand. To my mind, even the technical and medical staff often find it too detailed, boring, and sometime irrelevant. As an investigator, I would like an informed consent to be precise using simple language. Unfortunately, legal requirements are such that it is difficult to change the document, particularly when it involves an international study. I wish such documents could be made country-specific, although they are available in native language. There is no need to inform the subject of almost the rare possible side-effects and rare scenarios. It seems that the sponsor is doing his bit as laid down under the law, but I am not sure if it is appropriate for a particular subject. Therefore, as an investigator, I feel particular difficulty in convincing patients to agree to the study and sign the document. They often get confused added to this is an element of mistrust, and the subject tends to consult others, from whom they get conflicting advice. Those could be more educated relatives of other doctors. In view of this, the dropout rate for signing the informed consent is almost 50%.

ETHICS COMMITTEES

Ethics committees are large and fairly representative if properly formed. Unfortunately, some members of the ethics committees may not be very well versed with procedures and particularly not well versed with the delicate intricacies of the protocol and the details of the study. There are training programs and workshops for ethics committees' members, but this may not be happening in all ethics committees. It has also been noted that some members of the ethics committee may be too dogmatic and unaccommodating to the views expressed in the protocol or impervious to the views of other members. I think there is a need for better training of ethics committee members. The other problems with ethics committees are that they may not be meeting regularly, and sometime the quorum is not complete, in that case, the investigator has to wait for the next meeting of the committee, resulting in loss of crucial time. In some institutions like AIIMS, the ethics committees have too many projects to handle, and it can become a problem for members to thoroughly go through all the details. I personally feel that there is no need for 12-13 member committees, as it makes the committees unwieldy; a 5-member committee could be more effective and cohesive.

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COMPENSATION

It is necessary to offer compensation for injury sustained during the study due to trial drug. However, the rules and regulations for this have not been finalized in India. There are proponents of high compensation to trial subjects who have suffered injury. However, the exact definition of injury has not been clarified. It is rather disturbing to note that there is a recommended to be paid to subjects if the trial medication has not achieved its projected efficacy. This is unacceptable.

On the other hand, there has been misuse of clinical trials in India; some trials have been carried out without authorization, and some others have been carried out

without supervision and without due diligence. As an investigator, I feel that a proper system needed to be put in place for an appropriate compensation. It is also not clear as to who will decide on the amount of compensation, is it the investigator or the ethics committee? Or as some have suggested, a compensation committee? The compensation cannot be allowed to be too high, as it will deter future research and investment into research, and at the same time, it can't be allowed to be too low. Proper ethics would be to strike a moderate balance, keeping the socio-economic and internal factors of the situation in mind. These recommendations may have to be country-specific.

POST-TRIAL ACCESS

This is important, as it has sometime been seen that a certain toxicity or adverse event of a drug cannot be picked up during the trial. This is because the trial is often done in strict and ideal conditions, often limiting the trial to patients with P.S. of 0-II. However, after the approval of study drug, the drug is used by various physicians, even in patients who have compromised performance status and other organ functions; in this situation, serious adverse effects of the drug that were not known before come to light. Moreover, the drug is often used by a wider population of doctors who may not have had enough training or knowledge of the new drug. I, therefore, feel that post-trial surveillance study, which is also called as phase IV study, should be carried out for all new drugs for 2-3 years in substantial number of patients and submitted to authorities for information and wider dissemination. Unfortunately, the infrastructure for such type of monitoring is inadequate in India at moment and needs to be developed.

STUDY DESIGNS

In international and multi-center studies, it is difficult to change the design of the protocol. It is like take it for leave it situation. But, in these studies, one has to assess if the trial is appropriate to Indian situation; for example, if a trial is carried out in a disease that is common abroad but rare in India, the justification for such study may be poor in India. However, in the trials designed within India, one has to address the issue of safety within the context of achievement of objectives. Investigators must have experience in the field, in which they are going to conduct the trial.

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