VIEWPOINT

Role of ethics committees in medical research

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Having worked on the institutional review boards (IRBs—also known as ethics committees) of some institutes, I have a few comments to make on their role in research planning.

Every research institute should formulate a policy statement, which should be made available to the IRB. It should mention the type of research it will undertake, e.g. pre-clinical toxicology, animal studies in pharmacology or pathology, epidemiological surveys, clinical trials involving patients and studies using healthy volunteers, depending on its resources and infrastructure. This will help in deciding the types of studies to be avoided. The purpose of research—the benefits to be expected from the point of view of its staff, clients, students, society in general or the local community and the institute itself—should be revealed in this policy.

Every research protocol should be scrutinised and cleared by a scientific advisory committee before it is presented to the IRB. Proposals from abroad should have been scrutinised and cleared by an academic body in that country. The local committee may suggest modifications to suit local conditions.

The IRB is not expected to examine the technical details and statistical design in depth. It considers mainly the interests of research subjects. Participating research workers, clinical and para-clinical staff, administrative staff and the institute as a whole may also be objects of its review to some extent. Taking into consideration the source of funding, study objectives, and the welfare and rights of volunteers, patients or (in animal research) animals, the IRB can suggest suitable modifications to the plan or reject it totally.

The IRB should approve the information and consent forms to be presented to the patients or volunteers recruited for the study. These documents should be in simple language and contain no inducements.

Approval of the IRB should be for a specific period of time, during which the researcher is expected to report to the IRB the occurrence of any unexpected adverse events, difficulties encountered in the work and the progress of the work in general. The IRB has the right to stop the study, modify the protocol or deny further extension of the initial approval if it thinks that the study is not proceeding satisfactorily. For an imported project, guidelines provided by agencies responsible for the protection of rights in the parent country will be useful in continuing the review.

Data obtained during the course of the study, the results of data analysis and conclusions drawn from these results are important concerns from the points of access, custody, ownership, secrecy and publicity. These must be clarified in the research proposal. The IRB must insist that the funding agency or the sponsor will have no access to raw data and individual records. They will be submitted a report in a format similar to that of a paper sent for publication. Interim reports of progress of work may be given for release of instalments of grant. The final analysis should always be made by an academic institute.

The identities of the patients or volunteers must be guarded in most studies. If leftover biological material will be preserved and used in another study, informed consent forms must mention this possibility. The protocol should also clarify whether the individuals will receive the results of investigations performed on them, either immediately or after a period.

The institute and the IRB should insist that the study results are quoted only in scientific literature or technical reports submitted to regulatory authorities and not used for media publicity aimed at the lay public.

The working of the IRB involves extensive documentation. A properly designed research project is educative from the point of view of record keeping, which proves useful to the researcher in the long run.

To conclude, one must understand that the IRB is an important tool, which can be used to put into practice the concern expressed by the medical profession about medical research nearly 40 years ago in 1964 in Helsinki, and which continues to be expressed to cover a wider field.