Ethics Committee

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INTRODUCTION

Research in biomedical sciences has produced substantial social benefits but has also posed troubling ethical issues. The need to regulate such research culminated in the drafting of the Declaration of Helsinki, the ethical guiding document for human experimentation.

The Declaration of Helsinki and its further revisions, however, cannot in isolation improve the ethics of research. That requires 'people' to apply international codes to local circumstances and ensure implementation of research ethics processes.[1] One such mechanism, as prescribed in the Declaration, is the 'independent ethics committee' (IEC)* or the 'institutional review board', referred to by the acronym IRB.

WHY ETHICS COMMITTEES?

The function of the IEC / IRB is to oversee and monitor any clinical research project, thereby ensuring adherence to scientific, ethical and legal guidelines.[2] In both these functions the IRB is charged with assessing the scientific merit of research studies and assuring respectful treatment and safety of research participants.[3] Thus, ethics committees are required to meet the mandate of the declaration of Helsinki, to protect study subjects (their well being, rights and confidentiality) and to make clinical research socially respectable and acceptable to regulatory authorities and journal editors.

COMPOSITION OF AN ETHICS COMMITTEE

An IEC / IRB comprises both professionals and community representatives. It must have a minimum of 5 members of varying backgrounds; at least one member must be from a non-scientific area and at least one must be unaffiliated with the institution sponsoring the IRB.[4] The committee should include at least one member with a thorough knowledge of the scientific aspects of clinical research and of methods of research synthesis.[5] A legal expert, social scientist, theologian and a women's representative, would be the desired composition. The recommended number of members is twelve to fifteen.[6]

As per the Declaration of Helsinki, the ethical review committee must be independent of the investigator, the sponsor, or any other kind of undue influence. While the chairperson is preferably from outside the institution, the member-secretary may belong to the same institution that would conduct the business of the committee. The committee should be in conformity with the laws and regulations of the country in which the research experiment is being performed.[7]

Committees have the power to co-opt members, especially when dealing with new technologies such as genetic research. The value of such a temporarily co-opted specialist member is immense.[5] Independence and competence are the two hallmarks of an ethics

* IEC: a committee – institutional, regional, national or supranational"

committee.[6]

ROLE OF THE ETHICS COMMITTEE IN CLINICAL RESEARCH

Ethics committees are charged with overseeing all aspects of human research.[8] Their main role is to assess both the scientific and ethical aspects of submitted protocols. The research protocol must be reviewed and approved by a local IRB before commencing a clinical trial. The committee should be satisfied that investigators who take on research commitments, can conduct these studies adequately. It is empowered to exempt, approve, disapprove or require modifications in the submitted protocol of proposed studies. Its subsequent responsibilities include evaluating the annual progress report, approving amendments and taking stock of any adverse events.[5,9,10] Thus, a clinical trial is subject to continuing IEC / IRB review until closure.[11]

Broadly speaking, ethics committees have a wider responsibility to promote public interest by helping to ensure that relevant research is done, that research efforts are not being duplicated, and that patients are not being denied the benefits of already established effective therapies.[12]

FUNCTIONING OF AN ETHICS COMMITTEE

Each ethics committee should have its own standard operating procedure. The ethical review should be done through formal meetings with a proper quorum. Efforts should be made to reach a unanimous decision; if not, the proposal could be voted upon, voting rights being allowed to attending, permanent members only. The protocol amendments also need to be approved either by the full committee, if important, or by the Chairman's action, if minor (expedited approval).[13]

PROCEDURE TO OBTAIN APPROVAL

Most ethics committees have a format designed for submission of a protocol for review. The investigator is responsible for obtaining approval and for providing the necessary documents before commencing a clinical trial. The main documents that need to be submitted include:

- Protocol and case record form (CRF)
- Informed consent form (in a language understood by patients)
- Subject recruitment procedure (and documents such as a patient information leaflet in a language understood by patients) related to it
- Investigator brochure (a collection of data consisting of all clinical as well as non-clinical information available on the investigational product prior to the onset of clinical trial)
- Curriculum vitae of all investigators and the facilities at their disposal
- Details of the research grant and compensation available to the subjects
- Plans for publication of results, whether positive of negative
- Regulatory clearances (e.g. from the Drug Controller of India)

Most ethics committees charge a nominal fee for providing their services.

SCOPE OR DOMAIN OF THE ETHICS COMMITTEES

To assess the merit of a project, the IECs / IRBs must ask some basic questions:

- Does the project ask an important question?
- Will the study design allow that question to be answered?
- Are the risks to the research subjects acceptable?
- Will the autonomy of the subjects be respected by their informed consent being obtained?

Financial questions, such as "Can the trust afford this study?" should not be a problem for the ethics committee.[14]

PUBLICATION AND ETHICS COMMITTEE

The accountability of IECs / IRBs would improve if they ensure that the results of the trials that they approve are publicly available within a reasonable period of time after completion of data collection.[12] Rarely do ethics committees demand as a condition of approval, that any research project be submitted for publication. Certain IRBs in Australia have, however, adopted this

requirement for all projects involving human or animal subjects.[15]

FUTURE CONSIDERATIONS

Recently, there was a recommendation for creating a human research participant protection program. This would in effect replace the existing IECs / IRBs. This recommendation stems out of the fact that the present system of research review is overloaded and not free from bias. In place of IRBs, three reviewing bodies, one for scientific studies, one for potential conflicts of interest and a third for ethical reviews would exist. A consolidated final decision would be made based on all the three reports.[16]

CURRENT SCENARIO

Even today, examples of unethical research are reported regularly, with researchers dazzled by the potential scientific rewards, forgetting the moral and humane principles to which they should adhere. Although the ethical review process in many, particularly developing, countries is weak or inadequate, it does not justify any omission.[17] Ethics committees thus continue to be a vital safeguard for human experimentation.[14]

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