

Ethical review committees in Sri Lanka: a national framework is required

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Abstract

A questionnaire based study to review the status of the Ethical Review Committee (ERCs) was conducted in universities and research institutes involved in bio-medical and psycho-social research.

Questionnaires were sent to 37 faculties of 11 universities. Thirty faculties responded. The 6 medical faculties were among the 8 faculties that had ERCs. Questionnaires were sent to 10 research institutes and 3 associations. Among 8 institutes and 2 associations that responded, only the Medical Research Institute and the Sri Lanka Medical Association (SLMA) had ERCs. Fifty percent of the ERCs had a specific application form and there was no uniformity in the information obtained from the researchers. Some application forms lacked essential information relevant to ethical review. Information on availability of consent forms, source of funding, investigations, control selection, review of literature, co-investigators' information, educational qualifications of the investigators are some of them.

Sixty percent of ERCs had only academic staff or doctors as committee members. The recruitment of members to the committee did not follow a formal process and no institutional guidelines were available for ERC committee members.

In the current context there is a need to establish a national framework for ethical

review in Sri Lanka for educating researchers and to regularize ethical review of research.

Introduction

At present much bio-medical research involving human and animal subjects is being conducted in Sri Lanka. While many of this research goes through a process of ethical review it is possible that some projects are not screened.

However it is a requirement of many internationally published bio-medical journals that a certificate of ethical clearance be available for the research study to be published. The purpose of an Ethical Review Committee (ERC) in reviewing biomedical research is to contribute to safeguarding the dignity, rights, safety and well-being of all actual or potential research participants (1). In other words, the goals of research should never be permitted to override the health, well being and care of research participants. ERCs should also take into consideration the benefits and burdens of research be distributed fairly among all groups and classes of society (2).

ERCs should provide independent, competent and timely review of ethics of proposed studies before commencement of the research. They also need to ensure that there is regular evaluation of the ethics of ongoing studies that received a positive decision. ERCs should be multidisciplinary

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and multi-sectoral in composition, including relevant scientific expertise, balanced age and gender distribution and lay persons representing the interests of the community. Clear procedures for recruiting potential ERC members should be available as ERCs need to have independence from political, institutional, professional and market influences (3).

Objectives

The study was done to determine the existence of ERCs in Sri Lanka and to study the composition and mode of operation of the existing committees. The data was compared with those recommended by international guidelines.

Methodology

Information was requested from all universities and institutes involved in bio-medical research in Sri Lanka. All faculties of medicine, arts and humanities, science, agriculture and social science research institutes and main professional associations were included in the study. Data were collected using a self administered questionnaire posted to deans of faculties and heads of research institutions.

A copy of the application form used by the respective ERCs for ethical review was requested from all institutes included in the study. The non responders were contacted by telephone and relevant officials were interviewed. The questionnaires and relevant application forms were analyzed.

Results

Questionnaires were sent to 37 faculties of 11 universities. Thirty faculties responded. Eight faculties had ERCs and among these

6 were independent committees (Medical Faculties of Universities of Colombo, Sri Jayawardenepura, Ruhuna, Kelaniya, Jaffna and Faculty of Arts, University of Colombo) while 2 were sub-committees of the research committee. (Peradeniya Medical and Dental Faculties) All six medical faculties had ERCs. Four medical faculties had specific application forms designed for the purpose. All eight faculties invited the applicant for interview if further clarifications were required.

Questionnaires were sent to 10 research institutes and 3 associations. Eight institutes and 2 associations responded. Among institutes only the Medical Research Institute had a committee and there was no specific application form. Among associations, the Sri Lanka Medical Association (SLMA) had an ERC and an application form. The applicant was called for an interview if clarifications were required.

Project title, principle investigators' information, objectives of the study, research methods, details about medical procedures/interventions/treatments, data analysis plan, consent procedures, subject selection criteria, potential risks to the participant, benefits, incentives and payments to the subjects were details requested in the application forms and were common to all application forms reviewed. All ERCs requested information on the maintenance of confidentiality of data in their application forms.

One ERC of a Faculty of Medicine also requested information from applicants on specific invasive procedures which was included in the application form as a separate table consisting of a list of invasive and non invasive procedures done on human subjects and the applicant was

expected to tick the relevant box. They also had separate paragraphs pertaining to use of radioactivity, x rays, medicinal products, medical devices or equipment on study subjects.

Information on the informed consent process, source of funding, investigations, control selection, review of literature, investigators suitability and experience for the proposed study, provisions made for receiving and responding to queries and complaints from research participants were lacking in some application forms. None of the ERCs evaluated the ethics of ongoing studies that received positive decisions.

The majority (60%) of the ERC's did not have a specific time frame for process and review of the applications submitted and this varied from 1-3 months from the date of the receipt of applications.

The composition of the ERCs varied among different committees. Sixty percent (6/10) of the ERCs had only academic staff members/ doctors of their own institute as committee members, whereas the remaining four committees had members from different non-medical professions as members.

The recruitment of members to the committee did not follow a formal process of evaluation and no statements on candidacy that includes an outline of duties and responsibilities of members were available to committee members of any of the ERCs. No institutional guidelines were available for ERC committee members.

Three out of the ten ERCs requested a nominal processing fee (range Rs 250 to Rs 1000) for ethical review of research studies.

Five institutes that do not have ERCs requested information and guidelines on

setting up of ERCs in their respective institutes although this was not surveyed for in the questionnaire used for the study.

Discussion and Recommendations

Except for the faculties of medicine majority of the other faculties in universities, research institutes and associations which publicize research do not have a regularized process for ethical review of bio-medical research. Even when an ethical review program was in place, the information requested in the application forms was inadequate and ethically relevant information was lacking in some application forms. The application form for ethical review should address scientific design and conduct of the study, recruitment, care and protection of research participants, issues on confidentiality, informed consent process and relevant community considerations.

The Nuremberg code, 1947 lists the different elements in a study protocol that should be reviewed before providing ethical clearance for the study. However the ERC's in Sri Lanka do not have a uniform protocol where all these elements are addressed in the review process. In all ERC's the process of review was incomplete as one or more of these internationally recommended elements were not addressed during the review of applications. For example a full description of the process of obtaining informed consent has to be reviewed thoroughly as the voluntary consent of the human subject is absolutely essential. The documents of information on the project and informed consent forms should be in a language that could be understood by the potential research participants.

The ERC's in Sri Lanka recruited members to the committees in an ad hoc manner and there was no clear procedure for identifying

suitable members. Furthermore, once the members are appointed to the committee no clear guidelines are provided that would facilitate their functioning as effective members. With regard to ERC committee membership, clear procedures for identifying or recruiting potential members for ERC should be established (3). Once the committee is selected the conditions of appointment should be made available to the members.

Majority (60%) of the ERC's did not have a specific time frame for review of applications. It is also important to review the applications sent for review in a timely manner. It is recommended that the decision be communicated to the researcher within two weeks of the meeting. In the case of a conditional decision, any requirements by the ERC including the suggestions for revision should be clearly stated to the researcher. In the case of a negative decision, the reasons should be clearly stated (4).

ERC should establish a follow-up procedure for following the progress of all studies for which a positive decision has been reached, from the time the decision was taken until the termination of the research. This aspect of review was not practiced by any of the ERCs in Sri Lanka. The review intervals are generally determined by the nature and events of research projects. It is recommended that each research project should undergo a follow-up review at least once a year (3).

During the study many faculties and institutes requested information regarding setting up of ERCs in their respective institutes. Many internationally approved guidelines are available for establishing properly functional ERCs in research

institutes and universities (5, 6, 7, 8, 9). Thus in the current context, establishment of a National framework for providing guidance on setting up ERCs in institutes that conduct biological and psycho-social research would be an important first step in regularizing the process. This would also assist in reforming the existing research committees in the island.

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