Agenda Item 2.1.3 - Ethics in Health Research – An update on Ethical Review Mechanisms
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1. Introduction

Ethics has been a fundamental concern of health and medicine since early times and dealt with the formal obligations and responsibilities of physicians. The Hippocratic oath clearly mentioned the principal concern of physicians for the welfare of patients and the clear admonition to do no harm. This is true since ethics is related closely to humanity, which embodies in the social interaction of every human being.

With the ushering-in of the advancement of biotechnology, new medical procedures and therapeutics have undergone tremendous changes. They have raised many issues related to ethics, stimulating public interest and concerns. There is an increasing need for the strengthening of ethical review mechanisms for biomedical researches, which try to experiment with human beings to find new scientific innovations for the benefits of mankind. It becomes mandatory, as it would safeguard the dignity, the rights, the safety and well being of all actual or potential research participants.

The Secretariat Committee on Research Involving Human Subjects at the WHOHQ in its distribution letter dated February 18, 2000 on the above subject has stated the definition of “research involving human subjects” as, quoted: “Any proposal relating to human subjects including healthy volunteers that cannot be considered as an element of accepted clinical management or public health practice and that involves either physical or psychological intervention or observation, or collection, storage and dissemination of information relating to individuals.” This definition relates not only to planned trials involving human subjects but those researches in which environmental factors are manipulated in a way that could place incidentally exposed individuals at undue risk”. Bearing in mind of this definition, the ethical review mechanisms are therefore entrusted to hold the cardinal principle of research involving human subjects, which is “respect for the dignity of persons”.

In the 25th session of SEA-ACHR held at Bali in April 2000, a review on the “Operational guidelines for ethics committees reviewing biomedical research” was made and the Committee came with recommendations that:

1) countries should undertake situation analysis on their ethical review processes and mechanisms for reviewing health research, in particular, research involving human subjects; and
2) countries should review their curricula on biomedical and health ethics, including ethics in health research, in medical, paramedical and health training institutions.

The Regional Office conducted a review of the ethical review mechanisms at national and institutional levels and the following paragraphs provide an overview of the regional analysis, and suggest a framework for future action in strengthening the mechanisms in SEA countries. A critical analysis was made on four main areas:

- the architecture,
- the institutional capacity,
- the activities performed and
- the challenges
2. The Architecture

2.1 The status

The information of Table 1 (Annex) showed how the ethical review mechanisms were organized in member countries of the Region. Except Bhutan and Maldives, all other reported the existence of national and institutional ethical review mechanisms (ERMs). Most of the national ERMs existed within the government structure, usually under the Ministry of Health.

The national ethical review board (ERB) is established within the structure of the Nepal Health Research Council (NHRC). Through a parliamentarian act in 1991, the Board has served as the main national institution responsible for technical and ethical review of all proposals submitted by the individual health scientists, national authorities, NGO, International NGOs and the universities.

The national core group for research ethics falls within the structure of the National Institute for Health Research and Development (NIHRD), an institute established under the Ministry of Health of Indonesia. In addition, each academic institution, which is responsible for producing post-graduate students and also for conducting research activities, has established an institutional ethical review committee (ERC). The national ERC of India falls within the structure of the Indian Council of Medical Research (ICMR), an autonomous institute established under the Ministry of Health and Family Welfare of India. In addition, each academic institution like AIIMS or PGMI-Chandigarh, which is responsible for producing post-graduate students and also for conducting research activities, has established an institutional ethical review committee (ERC).

The national ethical review committee has been established at the Office of the Permanent Secretary, Ministry of Public Health, Thailand. Similar to Indonesia, major academic and research institutions in Thailand have established each own institutional ERC.

The National ERB of Bangladesh is in the structure of the Bangladesh Medical Research Council (BMRC) which is an autonomous body under the Ministry of Health and Family Welfare. The ERC of the Bangladesh Medical Research Council was formed in 1979. There are institutional ERCs existed in many academic and research institutions.

The Institutional ERC of the Department of Medical Research (Lower Myanmar) (Ministry of Health) was established in late 1991 as Committee on Medical Ethics. In late 1992, the National Ethical Committee was formed and renamed as National Ethical Committee on Clinical Research in mid 1994 under Ministry of Health and headed by deputy Attorney General as chairman and Director General of the Department of Medical research as secretary. A few ERCs existed in other academic and health research institutions.

In Myanmar, various faculty of Medicine have their own Institutional ERC reviewing research proposals as well as those put up from other institutions in the Ministry of Health. The institutional ERC's guidelines of the Department of Medical Research (Lower Myanmar) and requirement for submission of proposal were updated in late 2001.
Although the annex table indicates that in Sri Lanka, Faculties of Medicine in Colombo and Ruhuna have ethical review mechanisms, it is informed that at present each of other six Faculties of Medicine have the ethical review mechanism. Relatively recent, the Medical Research Institute of the Department of Health has established a review committee that includes ethical review.

2.2 The Functions

The main purpose of an ethical review committee (ERC), either at national or institutional level, is to review biomedical and health research so as to contribute to safeguarding the dignity, rights, safety and well being of all actual or potential research participants. A national ERC has to provide necessary policy and technical guidance to the establishment or development of the institutional ERCs. Most national ERCs have developed the national ethical guidelines, in order use as a guide for all involved in promoting good ethical practice in the respective countries.

3. The Capacity

3.1 Memberships

The main principle for memberships of an ERC is to have a multidisciplinary and multi-sectoral in composition. Independence and competence are the two hallmarks of an ERC. The review showed that the size of members of the national and institutional ERCs in the Region ranged from four to sixteen (including the chairman of the committee). The notion of keeping large size of the ERC members, like those of the Faculty of Medicine, Ruhuna University of Sri Lanka, is that members are busy and keeping membership large will equip them better in seeking replacement when one member is unable to attend a meeting. In contrary, the institutions that keep small to average numbers of memberships (around eight) stated that too many members in the committee will make it more difficult to reach consensus opinion.

The national ethical guideline of the ICMR, India, recommended twelve to fifteen members as maximum and five as the minimum to compose a quorum. It also stated that the membership of the ERC should have an adequate representation of age, gender and community.

The national ERC of Nepal has set the criteria in appointing members of an ERC, which includes relevant scientific expertise, balanced age and gender distribution, and a person representing the interest and concerns of the community. The varying background of ERC members is encouraged to promote complete and adequate review of ethical part of research proposals.

The national ERC of Bangladesh Medical Research Council shows a good mix of members’ disciplines and expertise, consisting of clinicians and health experts from various disciplines of surgery, epidemiology, pediatric, obstetric and gynecology, as well as of non-medical disciplines of psychology, law and journalism. Lay member and religious leader are also included. Lawyers are also found in the membership of the national ERC of Nepal and institutional ERCs of Thailand.
In Indonesia, while the guideline encouraged having the representation from people who do not possess health/medical backgrounds such as the religious leaders, lawyers, journalists, linguists, laymen, etc., the clinicians dominated the national and institutional ERCs.

Mono-discipline membership does appear at the ERC of the Dental Council of Thailand where all members are dentists and the Dental Council elects them. Another example is the ERC of the Faculty of Nursing of Thailand, which consists of all women members. All ERCs studied so far do have much of women memberships.

The involvement and the attitudes of non-medicals toward ERC has been studied by Allen Walters (JME, 83). The study revealed that seven out of ten non-medical respondents mentioned their willingness if asked to be a member of ethical review committee which the reasons stated varied from the view that it was a "very important committee" to the feeling that it was "a necessary but an irksome job".

In Bangladesh, Nepal and India, the Council appoints the memberships. The members of the ERC of Bangladesh tare nominated for three years by an elected Executive Board of the Council. In Thailand, the memberships of ERC are based on election.

The average period of memberships of ERC is around two to four years.

3.2 Honorarium for ERC members and charges to the PI

There are variations on the financial support to the members, as well as how the work of the committee members is financed. Being as a part of the organizational arrangement, the ethical review core groups of the National Institute of Health Research and Development (NIHRD) of Indonesia received the honorarium for their work. The financial support comes from the annual budget of the institute. The honorarium received by member does not relate to the numbers of the proposals reviewed by each, but rather to the participation of the ERC members in the meetings conducted. The national ERC does not charge any fees to the principal investigators (PI) for its review.

The members of ERC of the Bangladesh MRC obtain honorarium for attending the Meeting. There is also provision of honorarium for the reviewers of the research proposals.

The ERC of Faculty of Medicine, University of Songkla, Thailand, also provided the honorarium to the external reviewers and did not make charges to the PI. However, the ERCs of the Faculty of Medicine, Chiangmai University and the Ramatibodi hospital, Mahidol University, Thailand, while providing honorarium for members, collected fees for ethical review.

3.3 Secretariat support

Secretariat support is required for keeping track records of the research proposals and related documentation. Most ERCs are functioning under the national research councils or analogous bodies, which have full secretariat support, and thus most of them used the main secretarial support. A few of ERCs have no secretarial support and thus, much of the works done were not properly recorded. An example from
Indonesia showed that many institutional ERCs were unable to identify the number of research proposals reviewed in the past years, and major reason being due to the lack of filing and documentation support. Some institutional ERCs have member secretaries, whose jobs were mostly for coordinating the works. It was also found that only 40% of the ERCs have secretariat services.

3.4 The Guidelines

All national or institutional ERCs had referred that their performance of works were based on the three principal international guidelines on ethics in health research, viz.: (1) the International guidelines of the Council for International Organization on Medical Sciences (CIOMS/WHO), (2) the Declaration of Helsinki of the World Medical Association, and (3) the Nuremberg Code.

In order to strengthen the work of the national and institutional ethical review committees in reviewing the health research proposals involving human subjects, WHO, through its Tropical Diseases Research Programme (TDR) developed a generic guidelines called - “The operational guidelines for ethics committee that review biomedical research”. This guideline is intended to facilitate and support ethical review in all countries around the world. The guide is based on a close examination of the requirements for ethical review as established in international guidelines, as well as on an evaluation of existing practices of ethical review in countries around the world. The guideline is neither to replace the national and local guidelines nor to supersede national laws and regulations but to complement. WHO’s guide provides the national and institutional ERCs on what the procedures to constitute ERC, the role, duties and responsibilities, the selection of ERC members, the procedure and mechanism of decision making, how to communicate decision to the PI, and the procedure to submitting research proposal.

Over the years, various bodies in national jurisdictions have laid down general and specific legal principles for evaluating and monitoring health research, especially in specific areas of scientific research entailing the use of human beings as subjects. The national ethical codes are now available for India, Indonesia (in the final draft version), Nepal and Thailand. These ethical codes are drawn from the universal principles, the international codes of ethics and the national social norms and values. A few examples are the “Code of Ethics for Medical Profession B.E.2526 VI” and the “Human Experiment of the Medical Council and the rule and regulation of the National Research Council of Thailand”.

Many national ethical guidelines such as those of Nepal, India and Indonesia have referred the WHO operational guidelines as their source of reference. Thailand and Indonesia have translated and adapted the original operational guidelines into local language and the local versions have been distributed widely to all institutional ERCs in respective countries.

4. The Activities

4.1 Procedure for submitting a research protocol

There is a common pathway followed by almost all ERCs in submitting research proposals for ethical review. As per the information from the available guidelines of many ERCs, the principal investigator have to submit a complete proposal with
the abstract and the consent form one month prior to the ERC periodic meeting. The Secretary of the ERC will forward the proposal to the ERC Chairman and later to assign each member of the Committee for review of the proposal.

The national ethical guideline of the ICMR-India provided detailed requirements for a principal investigator of health research whenever submitting a proposal for ethical review. An appropriate application in prescribed format has to be completed and sent along with the study protocol at least three weeks in advance. The application should include: clear research objectives and rational for undertaking the investigation in human subjects in the light of existing knowledge, recent CV of the investigators indicating qualification and expertise, subject recruitment procedure, inclusion and exclusion criteria for entry of subject of the study, precise description of methodology of the proposed research including detail information such as intended dosage of drugs, duration of treatment and details of invasive procedures, if any, a description of plans to withdraw or withhold standard therapies in the course of research, the plans for statistical analysis, procedure for seeking and obtaining informed consent including sample size, safety of the proposed intervention using drugs, proposed compensation and reimbursement of incidental expenses storage and maintenance of data collected during trial, plans for publications for positive or negative results and its ethical issues that might occur, agreement to comply with national and international good clinical practice protocols on clinical trials and the details of funding agencies.

The national ERC of the Ministry of Public Health of Thailand stated clearly in its guidelines for PIs that they have to submit 21 copies of the research proposal to the Committee 23 copies in case of research on HIV/AIDS). It also set 10 ethical criteria as the guidance for the researcher when submitting the protocol. The ERC of Bangladesh Medical Research council requested 5 copies for each proposal needing ethical review. One of the major complaints of the potential and existing researchers was the need for multiple copies, which was a heavy cost for some.

4.2 The ethical review

In most cases, the research protocol submitted to the Council or the Board or analogous bodies has to be reviewed first by the Scientific Committee for its technical credibility and relevance, before sending to the ERC. Most ERCs review the ethical aspects of research proposals.

In some cases, like the national ERC of Nepal and some institutional ERCs (e.g. the ERC of Mahidol University, Thailand or ERC of DMR, Myanmar) made the reviews of the proposals on both scientific and ethical aspects. The reasons for reviewing both aspects are: (a) memberships of both Committees being the same; (b) the number of research proposals received being small.

Some national and institutional ERCs used the common checklist forms to conduct the ethical review. The ERC of Bangladesh Medical Research Council has developed Application Form for Ethical Clearance. The Form includes a cheque list, list of documents to be submitted for ERC and guidelines for preparation of Abstract for ERC. In some countries/institutions, the ethical review is done individually based on the subject of interest.

The overall review process will take approximately 2-3 months, from the receiving date of the proposal until the final decision is made and notified to the persons concerned. Each year, the national ERCs of Nepal and Bangladesh received
around 200 proposals. In Bangladesh, proposals sponsored by many international agencies need ethical clearance from the ERC of BMRC for fund release and implementation. An institutional ERC in Thailand reviewed approximately 50 proposals a year, mainly related proposals on clinical trials.

4.3 The decision making

The national ERCs of Bangladesh, India and institutional ERCs in Sri Lanka and Thailand revealed that they have set up a quorum mechanism to reach decisions. The NERC of ICMR, India stated the quorum is reached when $2/3$rd of the majority is present. The decision-making through quorum was followed by 56% of 26 institutional ERCs in Indonesia. The national ERC of Nepal do not set quorum but need the presence of full members. In decision making, both the National and Institutional ERCs of the Department of Medical Research (Lower Myanmar) take a consensus decision of attended members. Although there is no set quorum, more than 50% of the invited members must be present.

Two institutional ERCs from the FoM Sri Lanka have indicated they did not meet the quorum twice in 1998 and once in 1999. Similar was mentioned by one institutional ERC in Thailand. The decision has to be postponed until another meeting when the quorum was reached. This, to some extent, has lengthened the preparatory time of the research.

None of the ERCs in the Indonesia mentioned the experience in rejecting research proposals, since the aim of many ERCs are that the ethical review should be a tool to provide advice and assistance. National and institutional ERCs of Myanmar and institutional ERCs in Sri Lanka and Thailand have the experience of rejecting proposals. However, no obvious reasons of rejection were available.

Kent (JME, 1999) had conducted a small study to understand decisions of ERCs concerning approval of research protocols. Mostly the decision came into the category of approved with request for changes which can be further classified into a) further explanations for the committee to provide aid in their deliberation, b) requests for changes to the design of justification for the design used, c) changes to the information sheets provided to potential participants of the study, d) change to consent procedures. Item c) came as the most common type of request to change. Kent concluded that these four classifications of requests could be seen as efforts to safeguarding the well being of potential participants (the principle of non-malfeasance), of promoting the scientific validity of the research (the principle of beneficence) and of enhancing the rights of the potential participants (the principle of autonomy).

Another study on the same topic mentioned that revision of the protocol on ethical aspects was to put more detail information on inform consent. The two studies validated that ERCs are really concerned about the safety of the participants involved and that attempts for revision are directed to protect participants' rights and endures the scientific validity of the study.

Whenever necessary the principal investigator may be invited to present the protocol to offer clarifications in the meeting. The guidelines on ERC of ICMR, India encouraged the representation of the patients groups or interest groups during the deliberations to offer their viewpoints. All ERC meetings have to be recorded properly.
The ERC of BMRC provides some guidelines while providing ethical clearance. The guidelines were laid down based on Declaration of Helsinki. The National Ethical Committee on Clinical Research reviews the proposals put up by the Institutional ERC, which need approval from the NEC on Clinical Research. In case of any change of Protocol or any unexpected or adverse affect the PI is advised to inform the Council.

Once ERC cleared the ethical approval of a protocol, ERC will issue a certificate of approval signed by the ERC chairman. In some institutional ERCS, the director or head of the concerned institute where the ERC belongs put its countersigned.

In most national or institutional ERCS in the SEA countries, the categories of the decision fall into “approved, revised and rejection”; and the confidentiality are kept.

As for record keeping, the hard copies of the decision made by the ERC along with the research proposals and related documents, the ICMR suggests to retain records at least 3 years and make it available to regulatory authorities.

4.4 Monitoring the studies after ethical clearance

Almost all of the ERCS reported of not undertaking the monitoring of the research studies as they felt it was out of their terms of reference. Otherwise, the ERC of Bangladesh still feels that after approval, monitoring is necessary but due to financial and human resource constraints it is not possible yet.

Once the ERCS approved and issued the ethical clearance (agreed or disagreed), their tasks are completed. However, many ERCS do request the principal investigators to send the report at least once during the study period and to provide one copy of the final study report.

5. Challenges and ways to future work

5.1 Transboundary issues

As medical technology continues to develop, the subject of health ethics has an ever-increasing practical relevance. It is more prompted by high-technology developments and related ethical questions on current issues such as cloning, organ transplant and bioterrorism. This makes ethics in health as not just ethics of research but also involves access, quality assurance and goodness and fairness of available resource allocation. Thus, health ethics covers not only particular advances in science and biotechnology, that raise ethical questions, but also on larger issues of equity such as those posed in multilateral international trade agreements and globalization and cost implications of new biotechnology which sometime threatens health systems to provide equal access.

It is also obvious a number of ethical dilemmas that have important health dimension come to a transboundary nature. The intertwined of ethical issues or ethical solutions becomes even stronger in SEA countries, due to the common backgrounds in culture, norms and values. Having the international rules and regulations on ethics in health being adopted as principles for ethical review.
mechanisms, it is valid to question whether it is timely to develop regional code of practice with agreed procedures to shape common expectations and offer public assurances on ethics of research involving human subjects in the Region.

Further, there is a need for international mechanisms to respond to those concerns in ways that are both sensitive to local need and values and equitable ensuring that the health of all people is protected by these measures.

5.2 Need for strengthening

Based on the overview of the ethical review mechanisms in SEA region, it can now be concluded that the development of ethical review mechanisms links closely with the developmental stages of national health research systems.

The member countries of the WHO SEA Region could be grouped into two categories: (a) countries with much advanced health research systems, and (b) countries with embryonic stage of health research systems.

It is clear that countries with much advanced health research systems showed well-structured ethical review mechanisms. These countries have well established national and institutional ERCs. National ERCs are usually embedded within the structure of the health ministries, whereas the institutional ERCs are existed at the respective institutions where health research is one of the main functions of those institutions. Nevertheless, the functions carried out by these ERCs of various countries are differed from a comprehensive to restrictive.

For those countries with the embryonic stage of the development of the health research systems, the unstructured ethical review mechanisms do existed. The review of the research proposals involving human subject was conducted by an ad-hoc group of experts who had been selected based on the individual capacity and interests.

With rapid advance of technology in health and medicine where new drugs or other health interventions have been invented day after day, health research involving human subject are unavoidable in all countries irrespective of the development of health research systems. Therefore, a regional policy direction and strategic plans to strengthen both groups of SEA countries have to be identified and further implemented. An expert group on ethics, consisting of multidiscipline and multi-sectoral nature, has to work on this.

5.3 Promotion of the national operational guidelines

The WHO operational guidelines for the ERC members to review research proposals involving human subject has been widely disseminated to countries, including SEAR member countries. It is expected that the WHO guideline is to be used as a common framework for conducting ethical review by all ERCs. However, there is very little knowledge on the dissemination of understanding, the further usage and the applicability of the operational guidelines at the local and / or institutional ERCs in the countries. These guidelines also need to be periodically reviewed to keep up with the ethical issues that arise with future research programmes.

The need has been well recognized, and at recent time this need is more acute because, apart from the mandatory clinical trials in new drugs, a number of diagnostic procedures, therapeutic interventions and preventive measures
including the use of vaccines are being introduced which required proper tests on human beings. Researchers should be helped and equipped with practical guide to identify and address, at an early stage in the design of their studies, the ethical issues likely to be raised. The guidelines on ethical issues should cover information on the importance of informed consent, issues in clinical trials, research with healthy volunteers, research using placebos, research with children, seriously ill-patients, disability persons, vulnerable groups, research on human tissues, genetic research, gene therapy, research on fetuses and xenotransplantation. The technical ethical guidelines produced by the ICMR-India for example, is found as the most complete and comprehensive guidelines in the region.

5.4 Capacity strengthening

Majority of the responses from the SEARO self administered questionnaire stated the importance to equip the ERC members with optimum knowledge and skill on reviewing research proposals involving human subjects. It is well recorded that there is a great variation on the knowledge and skills of the ERC members in this aspect. Many ERC members perform the review only based by individual experiences. It is also mentioned that training on ethical review will create interest and will stimulate more professionals to join the ERC. In the case of Myanmar for example, the Institutional ERC of the Department of Medical research (Lower Myanmar) has limited trained health personnel to carry out the review, and as research needs grow, there is not enough manpower to conduct the review. Training more professionals will fill in the gap.

Capability strengthening on ethics in health research should also be expanded to the researchers to make them better prepared when submitting the research proposal for ethical review. Some ERCs have identified the low concern and low awareness of the principal investigators to submit proposals for ethical clearance; and this was due to little knowledge on the aspects to be put into concerns for ethical review.

A network for periodic socialization to update the recent development in ethics and health research is in time. The consultations among networks should widely involve the scientists, the sponsors of research involving human subjects, the business managers engaged in medicaments and health equipments, the health researchers, the health planners, the health system managers, the industries and donors, the policy makers, the patients and representatives of NGOs.

5.5 The role of WHO

WHO has a unique and important role to play. As the sole agency with authority to speak to and on behalf of all peoples health WHO is expected to provide support in the normative role in guiding the health professionals and the health agencies. In the context of ethics and health research involving human as subjects, WHO should focus on:

- To strengthen countries capability to deal with issues of research ethics,
- To play a major role as a centre of information on ethics and health to facilitate countries addressing recent development in health ethics.
- To support the further development of national and institutional ethical review mechanisms, and
• To enhance coordination on initiatives to promote ethical research involving human subjects to identify and address duplication and or gaps.

6. Conclusion

Ethics in health research, though practiced for many years in developed countries, it is just beginning to emerge as an important issue in developing countries, including SEA member countries.

The evidence has shown that SEA member countries can be categorized into two different groups in regard to the development stage of the ethical review mechanisms; and the difference was to some extent caused by different levels of development of national health systems. On the other hand, rapid advancement in health research for testing new drugs and medicine are unavoidable. Thus, it is imperative that the mechanisms for ethical review of researches involving human as subjects in developing countries, especially SEA member countries to be strengthened. A regional policy direction and strategic plans to strengthen both groups of SEA countries have to be identified and further implemented. An expert group on ethics, consisting of multidiscipline and multi-sectorial nature, should be organized to work on this.

It is well recorded that there is a great variation on knowledge and skills of the ERC members in many aspects of ethical review mechanisms. Similarly, great variations were identified on the researchers’ interests in submitting proposals when ethical review is actually needed. It is time to improve the technical capability of the ERC members for conducting proper review of research proposals involving human subjects and managerial ability to run ethical review mechanisms; and creating more awareness for the researchers in the importance of ethical review of research proposals.

Lastly, all countries of SEA region should put the development of their own national ethical guidelines as priority. Such guidelines will lay down general and specific principles in specific areas of scientific research entailing the use of human beings as subjects in medical research in their respective jurisdictions. The guidelines will also ensure that all national and institutional ERCs in the countries to work and function in the same directions.
REFERENCES


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Table 1: The status of national and local/institutional ethical review committees (ERCs) in SEA countries

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<thead>
<tr>
<th>Countries</th>
<th>Status of ERCs</th>
<th>Location</th>
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<tbody>
<tr>
<td>Bangladesh</td>
<td>National ERC</td>
<td>Bangladesh Medical Research Council (BMRC), Dhaka</td>
</tr>
<tr>
<td>India</td>
<td>National, Institutional and Local ERCs</td>
<td>Central Ethics Committee of Human Research, ICMR, Ministry of Health, New Delhi, Nair Hospital and TN Medical College, Mumbai, All India Heart Foundation, New Delhi, Discipline and Ethics Committee, All India Institute of Physical Medicine and Rehabilitation, Mumbai</td>
</tr>
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<td>Indonesia</td>
<td>National Core Group for Research Ethics, Institutional and Local ERCs</td>
<td>NIHRD, Jakarta, Faculty of Medicine in 11 provinces, National Family Planning Coordinating Board, Drug and Food Administration, Eyckman Laboratory for genetic research</td>
</tr>
<tr>
<td>Myanmar</td>
<td>National and Institutional ERC</td>
<td>Department of Medical Research (Lower Myanmar)</td>
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<td>Sri Lanka</td>
<td>Institutional ERC</td>
<td>Faculty of Medicine, University of Ruhuna, Colombo</td>
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<td>Thailand</td>
<td>National, Institutional and Local ERCs</td>
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