

ETHICS REVIEW COMMITTEE GUIDELINES

*A Guide for Developing Standard Operating Procedures
for Committees that Review Biomedical Research Proposals*

Forum of Ethics Review Committees, Sri Lanka

FERCSL

2007

ETHICS REVIEW COMMITTEE GUIDELINES

*A Guide for Developing Standard Operating Procedures
for Committees that Review Biomedical Research Proposals*

Edited by

Dr. Malik Fernando

Dr. Vajira H. W. Dissanayake

Dr. Enoka Corea

Forum of Ethics Review Committees - Sri Lanka

FERCSL

2007

ETHICS REVIEW COMMITTEE GUIDELINES

A guide for developing standard operating procedures for committees that review biomedical research proposals

First Published, July 2007

National Library of Sri Lanka – Cataloguing in Publication Data

ETHICS REVIEW COMMITTEE GUIDELINES

*A guide for developing standard operating procedures for
committees that review biomedical research proposals*

Forum of Ethics Review Committees, Sri Lanka, 2007

ISBN 978-955-1747-00-8

1. Research Ethics
2. Clinical Ethics

Parts of this publication may be reproduced, stored in retrieval systems, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise without any modification and alterations to the contents, with acknowledgment of the source: Ethics Review Committee Guidelines, FERCSL, 2007.

Introduction

These guidelines have been produced to promote the use of standard operating procedures by ethics review committees that review biomedical research proposals involving human participants, tissue and data; and animals used in research in a medical setting. It is designed to enable ethics review committees throughout Sri Lanka to develop their own standard operating procedures to suit the administrative structure of their parent organisations, yet conform in essential details and content to a “national” model. The anticipated result would be a uniform approach to the task of assessing ethics conformity of research proposals. These guidelines lay the foundation for enhancing the quality of research through the best possible ethics review by ensuring optimum standards in the composition of the committees that review proposals and the operational procedures followed by them. They also emphasise the duty of ethics review committees to safeguard the dignity, rights, safety and wellbeing of all actual or potential research participants and ensure that animals, if used for research, are treated humanely.

Preface

The guidelines were drafted by Dr. Malik Fernando and the annexes were designed by Dr. Vajira H. W. Dissanayake and Dr. Enoka Corea. The draft documents were reviewed at The National Conference On “Responding To Emerging Ethical Issues In Research On Human Subjects: Working Towards A National Consensus” held at the Faculty of Medicine, University of Colombo, Colombo, Sri Lanka from 30 November 2006 to 2 December 2006. The conference was organised by the Ethics Review Committee, Faculty of Medicine, University of Colombo under the chairmanship of Prof. Nalaka Mendis in association with the Ministry of Healthcare and Nutrition, the Ministry of Science and Technology, and the World Health Organisation (see annex D for a full list of participants). The draft documents were then circulated to professional medical Colleges and Associations; editors of indexed journals published in Sri Lanka; and Faculties of Medicine and Dental Sciences of Universities in Sri Lanka seeking comments. Relevant sections of the guidelines were also discussed at two workshops organised by the Forum of Ethics Review Committees in Sri Lanka held on 23 June 2007 (Biological Samples and Human Genetic Data: Collection, Processing, Use and Storage) and 24 June 2007 (International Collaborative Research) (see annex D for a full list of participants). The feedback received was incorporated into the final document that was edited by Dr. Malik Fernando, Dr. Vajira H. W. Dissanayake and Dr. Enoka Corea. The other members of the Ethics Review Committee of the Faculty of Medicine, Colombo reviewed the final manuscript. The page setting and cover design was done by Dr. Vajira H. W. Dissanayake. The printing of this document was funded by the World Health Organisation.

Table of Contents

1.	The Role of Ethics Review Committees	
1.1	Terms of Reference	1
2.	Composition of Ethics Review Committees	
2.1.	Appointment	3
2.2.	Membership	3
2.3.	Composition	3
2.4.	Responsibility and indemnity	5
3.	Ethics Review	
3.1.	General Considerations	7
3.2.	Application for Ethics Review	7
3.2.3.	Proposals that need review	8
3.3.	Ethics Issues for Consideration by Researchers	
3.3.1.	Ethical justification and scientific validity	10
3.3.2.	Externally sponsored research and multi centre studies	10
3.3.3.	Informed consent	11
3.3.4.	Inducements to participate in research	13
3.3.5.	Compromised capacity for giving informed consent	13
3.3.6.	Benefits and risks to study participants	15
3.3.7.	Research participants from populations and communities in which resources are limited	16
3.3.8.	Equitable distribution of burdens and benefits in the selection of participants/groups	16
3.3.9.	Research involving children	17
3.3.10.	Research involving pregnant women	17
3.3.11.	Safeguarding confidentiality	17
3.3.12.	Right of compensation	17
4.	ERC Meetings	
4.1.	Procedure for Meetings	19
4.2.	Conduct of Meetings	20
4.3.	Quorum	21
4.4.	Conflict of Interest	21
4.5.	Chairperson's Review and Expedited Review	21
4.6.	Exemption from Review	22
5.	Elements of the Review Process	
5.1.	Social or Scientific Value	23
5.2.	Scientific Validity	24
5.3.	Fair Participant Selection	24
5.4.	Favourable Risk/Benefit Ratio	25
5.5.	Informed Consent Process	26
5.6.	Respect for Potential and Enrolled Participants and Communities	27
6.	Decision Making and Communicating	
6.1.	Decision Making Process	29
6.2.	Communicating a Decision	29

6.3.	Positive Decision	29
6.4.	Conditional Decision	30
6.5.	Negative Decision	30
7.	Follow Up	
7.1.	Submission of progress report(s)	31
7.2.	Publication of results	31
8.	Notification	33
9.	Documentation and Archiving	35
	References	37
	Annexes	
A.	Application for Ethics Review	39
B.	Information Sheet/Consent Form	51
C.	Ethics Review Evaluation Form	53
D.	Participants/Contributors	59

1. The Role of Ethics Review Committees

The Ethics Review Committee (ERC) is a committee established to review the ethics of medical research involving human participants, tissue and data; and animals used in research in a medical setting. The purpose of the ERC is to safeguard the dignity, rights, safety and well being of all actual or potential research participants and ensure that animals, if used for research, are treated humanely. The ERC should ensure the full review and evaluation of all ethical aspects of the research proposals it receives before they are carried out to make sure they follow ethical guidelines. The tasks of the ERC should be executed free of bias and influence.

The ERC has the authority to demand research protocol modifications, enforce and monitor all informed consent or patients' rights issues and to suspend or stop any research that present problems. The ERC serves as the conscience of the scientific research community and the protector of the human (or animal) participants.

The ERC should provide independent, competent and timely review of the ethics of the proposed studies. The ERC should also be involved in the on-going monitoring of the conduct of research projects that are approved by it.

The ERC is responsible for acting in the interests of potential research participants and the concerned communities, taking into account the interests and needs of the researchers, and having due regard for the requirements of relevant regulatory agencies and applicable laws.

1.1. Terms of Reference

Institutions that appoint Ethics Review Committees (see 2.1) should provide terms of reference that set out the work expected of the committees. The nature of the institution will determine what is required; and may include the following:

- 1.1.1. consider written applications and provide independent ethics review of biomedical research;

-
- 1.1.2. be available to researchers for consultation on ethical issues;
 - 1.1.3. develop standard operating procedures (SOP) for ethics review and ethical conduct of research in the medical field, within the limits of national/international guidelines;
 - 1.1.4. conduct and promote education and training in research ethics for clinicians, researchers and others, both within the institution and without, including medical and non-medical undergraduate and postgraduate students;
 - 1.1.5. educate and train ethics review committee members to ensure the quality and consistency of ethics review;
 - 1.1.6. liaise with other ERC in matters of common interest;
 - 1.1.7. advise, support and facilitate the work of other ethics review committees on ethics issues;
 - 1.1.8. inform relevant government agencies of matters that may have policy implications that come to their notice during ethics review;
 - 1.1.9. promote community awareness and consult with individuals, communities and government on ethics issues relating to research on human subjects;
 - 1.1.10. keep abreast with international developments in relation to health and ethics issues and liaise with relevant international organisations and individuals.
- 1.2. Any proposed research should be scientifically sound if it is to be ethically acceptable. It is ideal to have a scientific review committee previously review a proposal and find it scientifically valid. However, where there is no such separate review, ethics review committees need to consider scientific value and validity (justification, methodology, proposed analytical methods, etc.) as well as ethical issues (see 5.1 and 5.2).

2. Composition of Ethics Review Committees

2.1. Appointment

Ethics Review Committees (ERC) should be appointed by appropriate institutional authorities.

2.1.1. ERC should have the freedom to work independently and decide on the merits of proposals without interference within the institutional framework.

2.2. Membership

2.2.1. Membership requirements

Clear procedures for recruiting potential ERC members should be established. A statement should be drawn up of the requirements for candidacy that includes an outline of the duties and responsibilities of ERC members. The initial orientation and training requirements and continuing education of ERC members should be specified.

2.2.2. Terms and conditions of appointment

2.2.2.1. Appointments should be made for a limited term – say three years – with provision for re-appointment. A rotation system for membership should be considered that allows for continuity, the development and maintenance of expertise within the ERC, and the regular input of fresh ideas and approaches.

2.2.2.2. Procedures for reappointment, resignation, discontinuation of appointment (such as for non-attendance), etc. should be specified in the respective SOP.

2.3. Composition

ERC should be multidisciplinary, multisectoral, and pluralistic. Heads of institutions should not be members.

-
- 2.3.1. The number of members in the committee will, in general, depend on the number of fields from which they will be drawn. However, as a general guide, a minimum of 7 and a maximum of 12 to 15 are suggested. Non-medical scientists and other lay members should be included, with attention to gender and age balance. The committee should include at least one member who is not affiliated to the institution. The suggested composition of an ERC is as follows:
- Two to three persons with expertise in basic medical sciences, including statistics;
 - Two to three clinicians;
 - A person with knowledge of ethics of medical research;
 - A person with expertise in law;
 - A person with expertise in philosophy/social science;
 - A person with expertise in public health research/statistics;
 - A lay person conversant with social values.
- 2.3.2. A chairperson and a secretary should be elected by the members or be appointed by the institution or other appointing body. The duties and responsibilities of each post should be clearly stated in the SOP.
- 2.3.3. The quorum for meetings should be laid down together with its composition, e.g. ‘at least one lay member’, etc. (see 4.3).
- 2.3.4. Provision should be made to enable ad hoc appointments of expert consultants to the committee when an opinion in any area that is not represented by the membership is required.
- 2.3.5. Provision should be made for persons who are not members of the ERC to review research applications and offer their comments.
- 2.3.6. Whenever there is a possibility of conflict of interest members should declare their association with the proposal and withdraw from the deliberations (see 4.4).

2.4. Responsibility and indemnity

There should be clear understanding of who bears ultimate responsibility in the event of complaints and/or litigation by dissatisfied clients of the ERC or research participants.

2.4.1. ERC should have the freedom to work independently and be responsible for their decisions. Such decisions should be based on diligent examination of the proposals and the application of approved methodology. Provided there have been no shortcomings in the process, it would be just for the parent institutions or organisations to bear the ultimate responsibility in cases of litigation. Suitable indemnity should be provided for ERC members.

2.4.2. The advisability of obtaining appropriate insurance policies to meet the challenge of possible claims for medical expenses or compensation by research participants and claims from clients needs consideration.

3. Ethics Review

3.1. General Considerations

Ethics review committees should:

- 3.1.1. ensure that an ethics review process has taken place which is relevant and appropriate to the ethical principles of biomedical research, taking into consideration the basic ethical principles of respect for persons, beneficence, non-maleficence and justice, without compromising the scientific merit and quality of research;
- 3.1.2. support investigators through referral to relevant research support services as deemed appropriate;
- 3.1.3. ensure that project investigators have appropriate access to staff and services of the ERC;
- 3.1.4. ensure that formal investigator-hospital-industry agreements are in place in case of industry supported projects;
- 3.1.5. ensure that investigators declare conflict of interest – both financial and non-financial; and
- 3.1.6. monitor and review, where possible, the conduct of research approved by the ERC.

3.2. Application for Ethics Review

- 3.2.1. Any biomedical research involving human participants, tissue, data, or animals should undergo ethics review before commencement. A researcher, deemed by the ERC to be suitably qualified and experienced to be responsible for the ethical and scientific conduct of the research, should apply for ethics review of the proposed research on a prescribed application form. When developing application forms care should be taken to include in them questions that will generate information on all matters required by the ERC to reach a decision [see annex A]. Researchers should respond adequately to all questions in the application form.

-
- 3.2.2. Applicants should be informed of the following:
- 3.2.2.1. whether applications are accepted from persons outside the institution;
 - 3.2.2.2. whether applications for research using animals are accepted;
 - 3.2.2.3. fees, if any, that are payable and the mode of payment;
 - 3.2.2.4. method of submitting applications, i.e. hard copies, electronic copies, or both;
 - 3.2.2.5. some indication of dates of ERC meetings and lead time required for processing of applications, review and communicating decisions; and
 - 3.2.2.6. procedure for inquiries and follow-up.
- 3.2.3. Proposals that need review
- 3.2.3.1. All medical research that involves human participants, tissues and data should undergo ethics review before it commences.
 - 3.2.3.1.1. In medical research the primary intention is to advance knowledge so that society in general may benefit; the individual research participant may or may not benefit directly. Hence research involving healthy volunteers is permissible.
 - 3.2.3.1.2. Research requiring ethics review can be considered under two heads.
 - a) Research that is non-intrusive or non-invasive: such research involves making observations only without any direct interference. Such studies are entitled for waiver of the requirement for obtaining informed consent but ethics review is essential.
 - b) Research that is intrusive or invasive: such research involves physical invasion (such as use of diagnostic or therapeutic products, vaccines, venepuncture), psychological intrusion, invasion of privacy, etc. Such studies

require both informed consent and ethics review.

- 3.2.3.1.3. The use of personal medical records and samples without approaching or involving the patients concerned is in principle ethically acceptable provided confidentiality and anonymity are preserved. Such studies are entitled for waiver of the requirement for obtaining informed consent, but ethics review is essential (see 3.3.3.5 and 4.6).
 - 3.2.3.1.4. Medical epidemiology, though often unintrusive, should be subject to ethics review. This applies to research in nutrition and the social sciences as well.
 - 3.2.3.1.5. Ethics review is not required for studies that amount to quality control or medical audit provided that the results are not made available in a form that identifies the participants from whom the information was obtained (see 4.6).
 - 3.2.3.1.6. In general, it should not be the researcher who decides what should be reviewed. If in doubt, particularly if the results are to be published or presented as a scientific communication, an ethics committee should be consulted (see also 4.5 and 4.6).
- 3.2.3.2. All research that involves the use of animals should undergo ethics review to ensure that animals are humanely treated.
- 3.2.3.2.1. It is not a requirement that all ethics review committees that deal with research on human participants should also be available for review of research on animal subjects and vice versa.
 - 3.2.3.2.2. Ethics committees in institutions where animals are used for research in a medical setting (e.g. medical schools or medical research establishments) could conveniently deal with

research proposals involving both humans and animals.

3.3. Ethics Issues for Consideration by Researchers

3.3.1. Ethical justification and scientific validity: Research involving human participants, including research with identifiable human tissue and data, is considered justified and valid only when the design of the research is scientifically sound and the principal investigators and the other research personnel are competent. The methods to be used should be appropriate to the objectives of the research and the field of study. It should include a thorough knowledge of the scientific literature and other relevant sources of information. These should be adequately reflected in the research proposal submitted for review and approval to the ERC.

3.3.2. Externally sponsored research and multi-centre studies:

3.3.2.1. The term ‘externally sponsored research’ refers to research sponsored, sometimes financed, and wholly or partly carried out by an external international or national agency with the collaboration or agreement of appropriate authorities, institutions and personnel in Sri Lanka. The term sponsor refers to the individual or agency that is responsible for the design, planning, ethical conduct, safety evaluation, data analysis, and dissemination of output of the research. It may also be the principal funding agency.

- a) A local collaborator (co-investigator) from Sri Lanka with equal responsibility is essential.
- b) A written agreement regarding sample/data ownership, publication strategy (including issues such as authorship and the right of the Sri Lankan collaborator to publish data pertaining to Sri Lanka), and intellectual property rights should be in place.

-
- c) The ERC has responsibility to determine whether the goals of research are related to the health needs and priorities of Sri Lanka and whether any benefits of research are shared.
 - d) The ERC should ensure that the research is not in conflict with the culture and practices of Sri Lanka.
 - e) Transfer of biological material abroad should be in accordance with existing laws and regulations. The ERC should act with caution to safeguard the interests of local individuals and communities and, at the same time ensure that research is not hindered. Biological samples should only be used for the purpose stated in the research proposal and not for any other purpose. The fate of the biological material after the proposed research is concluded should be clearly stated.

3.3.2.2. Research projects designed to be conducted in a number of centres (multi-centre studies in different communities or countries) should be conducted in identical ways at each centre.

3.3.2.3. If the research is sponsored by an external organisation, the research protocol should also have been submitted for ethics and scientific clearance in the country of the sponsoring organisation and the ethical standards applied in Sri Lanka should be no less stringent than they would be for research carried out in the country of the sponsor.

3.3.3. Informed consent: Informed consent is a voluntary decision taken by an individual to participate in research and is essential for all biomedical research involving human participants, tissue and data. The principal investigator has responsibility to obtain voluntary informed consent – either verbal or (preferably) written – from all prospective participants or in the case of individuals who are not capable of giving informed consent (see 3.3.5), the permission of their guardians.

-
- 3.3.3.1. Information regarding the research should generally be provided in the form of an Information Sheet. These should be available in English, Sinhala and Tamil (see annex B).
 - 3.3.3.2. Consent should be obtained by signature on a Consent Form that should be explicit (i.e. state clearly what is being consented to) (see annex B), or
 - 3.3.3.3. Verbal consent should be certified by the investigator as being freely given, on a form for that purpose or at the head of a questionnaire, in front of an independent witness.
 - 3.3.3.4. The investigators have a duty to:
 - a) seek consent only after the participant has received and adequately understood all necessary information and the consequences of participation. Participants must be given as much time as is needed to reach a decision;
 - b) ensure that the participant understands that consent is being sought for research and that it may or may not include clinical care;
 - c) ensure that the participant understands that he/she is free to withdraw consent at any time without fear of consequences;
 - d) refrain from deception, undue influence, inducement or intimidation;
 - e) convey the information in a language and manner that is appropriate to the individual's level of understanding; and
 - f) give the participant ample opportunity to ask questions and respond to them honestly, promptly and completely.
 - 3.3.3.5. Medical records and biological specimens taken in the course of clinical care may be used for research without the consent of participants only if the ERC has determined that:
 - a) the research poses minimal risk;
 - b) the rights or interests of the participants will not be violated;
 - c) privacy, confidentiality or anonymity are assured;

d) the research is designed to answer an important question and would be impracticable if the requirement of informed consent were to be imposed (see 3.2.3.1.3 – use of medical records).

3.3.3.6. Biological specimens taken in the course of research should be used for research only with the consent of the participants and only for the purpose for which consent has been given.

3.3.3.6.1. The consent forms should specify the investigations or other purposes to which the specimens would be subjected.

3.3.3.6.2. If there is a subsequent change of purpose, consent should be sought anew for that changed purpose.

3.3.4. Inducements to participate in research: Participants may be reimbursed for loss of earnings, travel costs and other expenses incurred in taking part in a study. They may also receive free medical services unrelated to the research and have procedures and tests performed free of charge. Those who receive no direct benefit from the research may also receive a small sum of money for the inconvenience due to their participation in the research.

3.3.4.1. The payments, however, should not be so large or the medical services so extensive as to induce prospective participants to take undue risks or to participate in the research against their better judgement.

3.3.4.2. All payments, reimbursements and medical services to be provided to research participants must be approved by the ERC.

3.3.5. Compromised capacity for giving informed consent: Certain individuals or groups may have limited capacity to give informed consent either because they have limited cognitive capacity or because they have limited autonomy. In this situation, the risk of an intervention should not exceed those associated with routine medical or psychological examination of such persons. A small increase above

such risk may be permitted by the ERC, but only when there is an overriding scientific or medical rationale for such increase.

3.3.5.1. Limited cognitive capacity is seen at the extremes of life – in children and in the elderly – and in disease states and other instances where the individual is unable to understand, retain or process the information provided so as to communicate a valid decision. In such instances proxy consent should be obtained.

3.3.5.1.1. Consent for research involving children below the age of 16 years should be obtained from their parents or guardians. However, it is best to involve the child, whenever possible (depending on the age and degree of maturity), when obtaining such consent. The consent forms should be worded in such a fashion that it is clear that consent is being given on behalf of a child, with an indication of the relationship (see 3.3.9).

3.3.5.1.2. Consent for research on the elderly, where there is evidence of reduced cognitive capacity or interference with communication (e.g. for people with dementia or following a stroke) should be obtained from their next of kin.

3.3.5.1.3. Consent for research in other instances where the individual is unable to understand, retain or process the information provided so as to communicate a valid decision should be obtained from the next of kin.

3.3.5.1.4. A problem can arise with regard to obtaining informed consent from proposed research participants with compromised capacity to consent if they are institutionalised and the next of kin are not easily accessible. The management of the institution may not be the best authority to give consent; a visiting medical advisor may be a better

person to give consent together with the management.

3.3.5.2. An unrelated carer (e.g. a hospital “bystander”) would not be qualified to give consent on behalf of his/her charge.

3.3.5.3. Persons in fiscal custody (prisoners) and members of the armed services may have limited autonomy – they may feel that they are under compulsion to agree by virtue of the disciplined environment in which they live and therefore may not be able to give their consent freely.

3.3.5.3.1. The situation is aggravated if the researcher happens to be a member of the same hierarchy; e.g. the prison’s doctor or a service’s officer recruiting research participants from his own unit. A similar situation exists when research participants are recruited by hospital doctors from among their own staff including medical students.

3.3.5.3.2. Freely given consent can be assured if such participants are invited to volunteer through an advertisement or notice that contains a description of the proposed study, rather than through a direct approach.

3.3.6. Benefits and risks to study participants: The investigator must ensure that risks are minimised and any anticipated risks are reasonably balanced against the potential benefits in all biomedical research involving human participants.

3.3.6.1. Interventions or procedures that hold out the prospect of direct diagnostic, therapeutic or preventive benefit for the individual participant must be justified by the expectation that they will at least be advantageous to the individual participant as any available alternative. Risks of such beneficial interventions must be justified in relation to the expected benefits to the individual.

-
- 3.3.6.2. Risks of interventions that do not hold out prospects of direct diagnostic, therapeutic or preventive benefit for the individual participant must be justified in relation to the expected benefits to society (generalizable knowledge). The risks presented by such interventions must be reasonable in relation to the importance of the knowledge to be gained.
- 3.3.7. Research participants from populations and communities in which resources are limited: It is unethical to conduct research in a country or community if there is good reason to believe that a product developed or knowledge generated as a result is unlikely to be made generally available or applied for the benefit of the population of that country or community. It is therefore recommended that:
- 3.3.7.1. the research be responsive to the health needs and the priorities of the community in which it is to be carried out;
 - 3.3.7.2. the research participants have access to any products (drug or device) shown to be beneficial to the participants after conclusion of the study; and
 - 3.3.7.3. any intervention or product developed, including knowledge generated, should be available for the benefit of the people of Sri Lanka; the sponsor should undertake to make any such product available in Sri Lanka at a reasonable cost, through a prior written agreement.
- 3.3.8. Equitable distribution of burdens and benefits in the selection of participants/groups: Groups/communities to be invited to participate in research should be selected in such a way that the burdens and benefits of research will be equitably distributed.
- 3.3.8.1. The exclusion of certain groups or communities that might benefit from study participation must be justified.
 - 3.3.8.2. Overuse of certain groups, such as the poor, is unjust as they may be more easily induced to participate in exchange for small payments.

3.3.9. Research involving children. Before undertaking research involving children the investigators must ensure that:

- 3.3.9.1. the research might not equally well be carried out with adults;
- 3.3.9.2. the purpose of the research is to obtain knowledge relevant to the health needs of children;
- 3.3.9.3. a parent or guardian has given permission;
- 3.3.9.4. the consent of each child has been obtained after the child has been informed to the extent that the child's maturity and intelligence permits;
- 3.3.9.5. a child's refusal to participate or continue in research will be respected;
- 3.3.9.6. the research is conducted in a setting in which the child and parent can obtain adequate medical and psychological support; and
- 3.3.9.7. the parent or guardian is given the opportunity to observe the research as it proceeds, so as to be able to withdraw the child if they decide that it is in the child's best interest to do so (see 3.3.5).

3.3.10. Research involving pregnant women: Before undertaking research on pregnant women the investigators must ensure that:

- 3.3.10.1. prospective participants are adequately informed about the risks and benefits to themselves, their pregnancies, the fetus and their subsequent offspring and their fertility;
- 3.3.10.2. the purpose of the research is to obtain knowledge relevant to the particular health needs of pregnant women, their fetuses or to the health needs of pregnant women in general; and
- 3.3.10.3. where appropriate, such research is supported by reliable evidence from animal experiments regarding risks of teratogenicity and mutagenicity.

3.3.11. Safeguarding confidentiality: The investigator must establish secure safeguards to ensure the confidentiality of participants' research data. If the information collected and stored could cause harm or distress when

disclosed to a third party, the investigator should arrange to protect the confidentiality of such information; for example, by omitting information that might lead to identification of individual participants, limiting access to the information, anonymizing data or by other means. The investigator should inform the prospective participants about the measures that will be taken to protect confidentiality.

3.3.12. Right of compensation: Investigators should ensure that research participants who suffer accidental injury as a result of procedures or interventions performed exclusively to accomplish the purpose of research are entitled to free medical treatment for such injury as well as financial or other assistance.

4. ERC Meetings

Ethics review committees should provide independent, competent and timely review of the ethics of research proposals studies.

4.1. Procedure for meetings

Ethics Review Committees should develop suitable procedures to ensure that all applications are reviewed in a systematic manner.

4.1.1. The exact method employed will depend to some extent on the workload – the number of applications that need reviewing at every meeting.

4.1.1.1. If only a few proposals (2 to 3) need to be assessed at a time it would be practicable for all members to review the full applications including all associated documents.

4.1.1.2. If a large number of applications need assessing at each meeting it would be more practical if one member (principal reviewer) undertakes an in depth review including all forms, questionnaires, etc. and the other members review a summary containing essential details.

a) In this regard, appropriate construction of the “Ethics Review Application Form” facilitates making such a summary (see annex A).

b) The task of the principal reviewer would be facilitated by using an evaluation form that should be developed by the ERC (see annex C).

4.1.2. It would be helpful if the principal reviewer was empowered to discuss deficiencies, if any, in the application with the applicant and to request necessary revisions before the ERC meeting; this expedites processing.

4.1.2.1. The procedure may provide for the applicant, a co-investigator or a representative of the sponsor/funding

organisation to be invited to attend the ERC meeting when the application is taken up to elaborate on specific issues.

4.1.3. All applications should be discussed by the members present (except when an alternate procedure is allowed – see 4.5) and a decision made as to whether the proposal

- meets the required ethical standards;
- needs to be further clarified or revised; or
- is rejected.

4.1.4. At the conclusion of the meetings, all applicants whose proposals were discussed should be informed of the decisions of the ERC under the signature of the chairperson, secretary or other authorised person.

4.1.4.1. Ethics approval should be intimated together with any responsibilities and/or conditions, including the period of validity of the approval (see 6.3).

4.1.4.2. If clarifications or revisions are required, they should be explained clearly (see 6.4).

4.1.4.3. If the application is rejected, reasons should be given (see 6.5).

4.2. Conduct of Meetings

4.2.1. Meetings should be held on a regular basis at a time and place convenient to all members.

4.2.2. The frequency of meetings will depend on the number of applications that need reviewing.

4.2.3. The agenda should not be so loaded that sufficient time is not available for discussion.

4.2.4. Members should have had sufficient time to peruse the applications prior to the meeting. The principal reviewers, especially, should have had adequate time to review the applications assigned to them and to consult with applicants if necessary.

4.2.5. Meetings should be formal, presided over by the chairperson (or a senior member if the chairperson is absent), with minutes of the

previous meeting confirmed and time provided for other matters to be discussed after the applications are reviewed.

4.2.6. The proceedings of the meetings should be confidential; if applicants are invited, they should be present for discussion of their applications only. The same procedure should be followed if an independent (specialist) reviewer is invited to advise on any particular topic.

4.2.7. Minutes of ERC meetings should be maintained in a standard format.

4.3. Quorum

4.3.1. The minimum number of members required to form a quorum and any special requirements (such as “at least one lay member”) shall be laid down in the SOP (see 2.3.3).

4.4. Conflict of Interest

4.4.1. Conflict of interest is present and interferes with ability to make an objective evaluation when ERC members are investigators in the research protocol being reviewed or, for example, when a member is an advisor to a company whose product is being tested.

4.4.1.1. In such an instance the member/s should disclose conflict of interest and refrain from participating in the review process by leaving the meeting room.

4.5. Chairperson’s Review and Expedited Review

ERC procedures could, with advantage, incorporate provisions for dealing with applications that have no or only minor ethical issues and also for urgent applications.

4.5.1. Chairperson’s review

4.5.1.1. Most projects will require formal review by the full ERC. But there are some investigations that do not pose any ethical problems (ethically minor investigations), where there is no risk of distress or injury, physical or psychological, to the

subjects e.g. some epidemiology, some surveys on eating or smoking habits, assessment of patient information and education. Projects such as these should be the subject of an application but may not require review by the full committee.

4.5.1.2. The ERC may provide for the chairperson, alone or consulting another member, to receive proposals of such ethically minor investigations and to issue approval expeditiously, always reporting these approvals to the next meeting of the committee. When the chairperson is not satisfied that an investigation falls into this ethically minor category, the application should be referred for full committee review.

4.5.2. Expedited review.

4.5.2.1. Under exceptional circumstances of urgency (e.g. a patient with some rare or ill understood condition, epidemics, etc.) the chairperson in consultation with another member may give expedited approval, always reporting these approvals to the next meeting of the committee.

4.5.2.2. Wherever there is doubt, an application should go to the full committee.

4.6. Exemption from Review

4.6.1. Ethics review is not required for studies that amount to quality control, method validation, or medical audit provided that the results are not made available in a form that identifies the participants from whom the information was obtained (see 3.2.3.1.5).

4.6.2. Use of personal medical records without approaching or involving the patients concerned is, in principle, ethically acceptable provided confidentiality and anonymity are preserved. Such studies are entitled for waiver of the requirement for obtaining informed consent, but ethics review is essential (see 3.2.3.1.3).

5. Elements of the Review Process

Badly planned and poorly designed research that causes inconvenience to participants with possible risks will not produce useful or valid results and is considered to be unethical. It is the responsibility of the researcher to ensure that his / her research is of good scientific quality before making an application for ethics review. The ERC should review ethical issues only if the research is of good scientific quality. Scientific review should pay special attention to scientific value, validity and feasibility of the protocol and cite relevant scientific literature (if any) on the subject of the proposed research to justify the proposal. The procedure may make provision for a separate committee to review scientific validity.

The framework below is proposed to ensure quality and consistency of the ethics review process:

5.1. Social or Scientific Value

5.1.1. To be ethical, biomedical research must be valuable. If clinical research is without some possible social or scientific value, it would be considered a waste of resources and unnecessary exposure of human beings to potential harm. To be valuable, the treatment, intervention or theory will have to improve health and well being or increase knowledge. Clinical research with non-generalizable results, a trifling hypothesis or substantial or total overlap with proven results would not be considered to be socially or scientifically valuable. Also, research with results unlikely to be disseminated or in which the intervention could never be practically implemented (even if effective) is not valuable.

5.1.2. The ERC should ensure that there is a plan whereby results of scientific value would be disseminated.

5.2. Scientific Validity

5.2.1. To be ethically acceptable, research must be conducted in a methodologically rigorous manner. Scientifically unsound research in human participants is ipso facto unethical, in that it may expose participants to risks or inconvenience to no purpose. The ERC should ensure that:

- 5.2.1.1. the research has a clear scientific objective;
- 5.2.1.2. the research is designed using accepted principles, methods, and reliable practices;
- 5.2.1.3. the research has sufficient power to definitively test the objective with the smallest number of research participants;
- 5.2.1.4. a plausible data analysis plan is provided; and
- 5.2.1.5. the researcher possesses the necessary qualifications, experience and access to facilities to carry out the proposed study.

5.3. Fair Participant Selection

5.3.1. The recruitment protocol should ensure fair participant selection. Selection of participants should be carried out so that stigmatised and vulnerable groups such as those who are socially disadvantaged or those who have limited autonomy are not targeted for risky research and the rich and socially powerful are not favoured for potential research benefits. The following should be considered:

- 5.3.1.1. the characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, ethnicity, social status, limited autonomy); and
- 5.3.1.2. whether the inclusion and exclusion criteria have been selected to minimise risks and maximise benefits to individual research participants and society.

5.4. Favourable Risk/Benefit Ratio

5.4.1. Within the context of standard clinical practice and research protocol, risks must be minimised, potential benefits enhanced and the potential benefits to the individuals and knowledge gained for society must outweigh risk. The following should be considered:

- 5.4.1.1. justification of predictable risk and inconvenience weighed against the anticipated benefits for the research participants and the concerned communities;
- 5.4.1.2. justification for the use of control arms;
- 5.4.1.3. criteria for prematurely withdrawing research participants;
- 5.4.1.4. criteria for suspending or terminating the research as a whole;
- 5.4.1.5. adequacy of provisions made for monitoring and auditing the conduct of the research including safety monitoring;
- 5.4.1.6. the adequacy of the site, including the support staff, available facilities and emergency procedures;
- 5.4.1.7. the suitability of the investigator's qualifications and experience for the proposed study;
- 5.4.1.8. any plans to withdraw or withhold standard therapies for the purpose of the research and the justification for such action;
- 5.4.1.9. evidence of the safety of any intervention or therapy;
- 5.4.1.10. the medical care to be provided to research participants during and after the course of the research;
- 5.4.1.11. the adequacy of medical supervision and psycho-social support for the research participants;
- 5.4.1.12. steps to be taken if research participants voluntarily withdraw during the course of the research;
- 5.4.1.13. a description of any financial costs to research participants;
- 5.4.1.14. provision for compensation and/or treatment in the case of injury, disability or death of a research participant attributable to participation in the research;
- 5.4.1.15. the insurance and indemnity arrangements where applicable;
and

5.4.1.16. access to any products (drug or device) shown to be beneficial after conclusion of the study.

5.5. Informed Consent Process

5.5.1. Participants should be informed about the research and should provide their voluntary consent. Consent on behalf of those with compromised capacity to consent should be obtained from parents, guardians or next of kin as the case may be (see 3.3.5). The following should be considered:

- 5.5.1.1. the process for obtaining informed consent including the identification of those responsible for obtaining consent;
- 5.5.1.2. the adequacy, completeness, and clarity of written and oral information to be given to the research participants and, when appropriate, their representative(s);
- 5.5.1.3. justification for the intention to include individuals who cannot consent and a full account of the arrangement for obtaining consent for participation of such individuals;
- 5.5.1.4. assurance that research participants will receive information that becomes available during the course of the research, which is relevant to their participation (including their rights, safety and wellbeing);
- 5.5.1.5. provision made for receiving and responding to queries and complaints from research participants or their representatives during the course of research;
- 5.5.1.6. arrangements for informing the research participant's family doctor, if any, when appropriate, including the procedure for seeking the participant's consent to do so;
- 5.5.1.7. the process for obtaining informed consent from the next of kin when using organs and tissues from cadavers;
- 5.5.1.8. evidence that consent is truly voluntary and not due to deception, undue influence, inducement or intimidation; and
- 5.5.1.9. evidence that participants are informed that they are free to withdraw consent at any time without fear of consequences.

5.6. Respect for Potential and Enrolled Participants and Communities

Research participants should have their privacy protected and their well being monitored. Research protocols should contain the following, and they should be considered by review committees.

5.6.1. For individuals:

- 5.6.1.1. a full description of people who will have access to personal data of the research participants, including medical records and biological samples;
- 5.6.1.2. the measures proposed to ensure confidentiality and security of personal information concerning participants;
- 5.6.1.3. a description of any plans to make the study product available to the research participants following the research;
- 5.6.1.4. the measures taken to inform research participants about information that becomes available during the course of research, which is relevant to their participation (including their rights, safety, and well being); and
- 5.6.1.5. the measures proposed to inform participants of study results when appropriate.

5.6.2. For communities:

- 5.6.2.1. the impact and relevance of the research on the wider local community and on the specific communities from which the research participants are drawn;
- 5.6.2.2. the steps taken to consult with the communities during the course of designing the research;
- 5.6.2.3. the influence of the community on the consent of individuals and proposed community consultation during the course of the research;
- 5.6.2.4. the extent to which the researcher contributes to capacity building such as the enhancement of local healthcare, research, and the ability to respond to public health needs;

-
- 5.6.2.5. a description of the availability and affordability of any successful study product to the communities following the research; and
 - 5.6.2.6. the measures proposed to inform the community of study results when appropriate.

6. Decision Making and Communicating

6.1. Decision Making Process

The decision making process of the ERC should be clearly stated; e.g. by consensus, by vote, etc.

- 6.1.1. Members should withdraw from the process if there is conflict of interest.
- 6.1.2. A decision can only be made by a meeting that has a proper quorum.
- 6.1.3. All relevant documents must be present before a decision can be made.
- 6.1.4. Only members who participate in the review should be involved in the decision.

6.2. Communicating a Decision

ERC procedures should lay down the manner in which decisions would be communicated to applicants. Communications should be in writing under the signature of the ERC Chair, Secretary or other designated officer and include, but not be limited to, the following:

- 6.2.1. the specific identification number of the application;
- 6.2.2. the full title of the research proposal;
- 6.2.3. the name and title of the applicant(s);
- 6.2.4. a clear identification of the version number of all documents on which the decision was based;
- 6.2.5. the date of the decision; and
- 6.2.6. a clear statement of the decision reached.

6.3. Positive Decision

- 6.3.1. In the case of a positive decision a statement of the responsibilities of the applicant should be communicated (see 8.1).

6.3.2. In the case of a conditional positive decision, i.e. a decision where ethics clearance is granted subject to the researchers complying with conditions stipulated by the ERC, a statement of the responsibilities of the applicant and the stipulated conditions for acceptance should be communicated.

6.3.2.1. Written acceptance of conditions laid down by the ERC should be requested from the investigator.

6.3.3. The period of validity of the approval should be stated.

6.4. Conditional Decision

In the case of a conditional decision, i.e. where ethics clearance is not granted for the original proposal but a revised proposal would be accepted for consideration, any requirements stipulated by the ERC including suggestions for revisions and the procedure for re-reviewing the application should be communicated to the researcher. Any time limit imposed for reply should be stated.

6.5. Negative Decision

In the case of a negative decision a clear statement of the reason(s) for the negative decision should be communicated to the researcher including whether it may be submitted as a new proposal with appropriate changes. The right to appeal and procedure for re-review (if any) should be conveyed.

7. Follow Up

ERC should consider the advisability of monitoring progress of research approved by them.

7.1. Submission of progress report(s).

7.1.1. Progress reports may be called for at predetermined intervals – say every six or twelve months. For multi-year projects at least once a year. A final report should follow at the conclusion of the project.

7.2. Publication of results.

7.2.1. Confirmation of publication of results together with a reprint may be requested.

7.2.2. Publication is important in drug studies and evaluation of new therapies and procedures (clinical trials). Ethics approval may be conditional on registration of such studies in an appropriate clinical trials registry.

8. Notification

- 8.1. ERC should make provision to require researchers to keep the committees informed of:
 - 8.1.1. all cases of protocol amendments (other than amendments involving only logistical or administrative aspects of the study);
 - 8.1.2. all cases of amendments to the recruitment material (research participant information sheets or the informed consent forms);
 - 8.1.3. serious and unexpected adverse events related to the conduct of the study, for example adverse effects of drugs, and the response taken by the investigator; and
 - 8.1.4. any new information that may affect the risk/benefit ratio of the study.

9. Documentation and Archiving

- 9.1. All working procedures must be in writing. ERC should make provision for archiving all material relating to its work for a minimum period (e.g. five years) from the date of granting approval.

- 9.2. The material to be archived should include, but should not be limited to:
 - 9.2.1. the agendas of ERC meetings;
 - 9.2.2. the minutes of ERC meetings;
 - 9.2.3. one copy of all material submitted by applicants;
 - 9.2.4. correspondence by ERC members with applicants or concerned parties regarding applications, decisions, and follow-up;
 - 9.2.5. a copy of the decisions and any advice or requirements sent to applicants;
 - 9.2.6. all correspondence and other material received during the follow-up;
 - 9.2.7. ERC membership;
 - 9.2.8. ERC standard operating procedures;
 - 9.2.9. records on income and expenditure; and
 - 9.2.10. annual reports.

References:

1. Operational Guidelines of the Ethical Review Committee. Faculty of Medicine, University of Colombo. Colombo. 2005.
2. Ethical Review Committee Guidelines. Sri Lanka Medical Association. Colombo. 1999.
3. Guidelines on the Practice of Ethics Committees in Medical Research Involving Human Subjects. The Royal College of Physicians of London. London. Second Edition; 1990.
4. Operational Guidelines for Ethics Committees that Review Biomedical Research. World Health Organisation. Geneva. 2000.
5. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research. New Delhi. 2000.
6. Guidelines for Institutional Review Committees for Health Research in Nepal. Nepal Health Research Council. Katmandu. 2005.
7. National Ethical Guidelines for Health Research in Nepal. Nepal Health Research Council. Katmandu. 2001.
8. Emmanuel *et al.* "What makes clinical research ethical?" JAMA 2000;283:2701-2711.

These documents incorporate the ethical rules contained in the following International guidelines: The Nuremberg Code; International Ethical Guidelines for Biomedical Research involving Human Subjects prepared by the Council for International Organisations of Medical Sciences (CIOMS) in collaboration with the World Health Organisation; and the Declaration of Helsinki.

Application for Ethics Review – Part I

for official use

Application No:		Date Received:		/		/	
Reviewed By:		ERC Meeting Date:		/		/	
Decision		Date Informed:		/		/	

Type of Review Requested

Regular

Expedited *Please see ERC guidelines to determine whether this application qualifies for expedited review.*

1. Title of Project

2. Investigators:

Applications from investigators based overseas will only be considered if the project is done in collaboration with investigators based in institutions in Sri Lanka who take equal responsibility for the conduct of the study and who will appear as co-authors in any publication arising out of the study.

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact Nos:

Email Address:

Principal Investigator Co-investigator Supervisor

Signature

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact Nos:

Email Address:

Principal Investigator Co-investigator Supervisor

Signature

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Annex A

Contact Nos:

Email Address:

Principal Investigator Co-investigator Supervisor

Signature

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact Nos:

Email Address:

Principal Investigator Co-investigator Supervisor

Signature

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact Nos:

Email Address:

Principal Investigator Co-investigator Supervisor

Signature

3. Proposed starting and ending dates: *‡

Start Date End Date

*From initial recruitment of participants until completion of all data collection.

‡Retrospective approval will not be given for projects already started or completed.

4. Has ethics review for this study been requested earlier from this committee or another similar committee?

Yes* No

*Where?

*When?

*Result:

Application for Ethics Review – Part II

for official use

Application No:

1. Title of Project

2. Funding

Name and Address of Funding Source(s)	Amount
<input type="text"/>	<input type="text"/>

3. A brief summary of the research proposal in simple language (maximum 500 words)

4. Scientific importance and validity

4.1. What is the scientific importance of your study in relation to improving health care and/or knowledge on the subject?

4.2. Is your study an original one or a replication of a previous study?

Original Replication

If it is a replication study please justify.

4.3. Has this research proposal been subjected to scientific review by any other committee?

Yes No

If YES, what is the name of the committee?

4.4. Are the investigator's qualifications and experience appropriate to conduct the study?

Yes No

4.5. Are the facilities at the site adequate to support the study?

Yes No

4.6. How will the results of the study be disseminated?

5. Assessment of Risks/Benefits

5.1. Is the involvement of human subjects necessary to obtain the necessary information?

Yes No

5.2. Are there any risks (physical, psychological, social, legal, economic) to the participants?

Yes No

If YES identify them and state how you plan to prevent or minimize these risks?

5.3. Are there any benefits to the participants?

Yes No

If YES identify them. If NO what are the benefits to the community or health care system?

Annex A

5.4 Justify the potential benefits against the risks.

5.5. Is standard therapy going to be withheld from the participants?

Yes No Not Applicable

If YES, justify.

5.6. Is the standard of care the best available locally?

Yes No Not Applicable

If NO, explain.

5.7. Is the medical and psychological support for the participants adequate?

Yes No Not Applicable

If No, explain.

5.8. What is the procedure for dealing with adverse events?

5.9. What is the procedure for reporting adverse events?

5.10. Is there provision for compensation for participants who sustain injuries?

Yes No Not Applicable

If YES/NO explain.

5.11. What are the provisions for safety monitoring and termination of research?

5.12. What is the possibility of an effective intervention, if found, being available to the population?

6. Respect for the dignity of the research participants

Informed consent

6.1. Write briefly your procedure for obtaining informed consent.

6.2. Who will obtain consent?

6.3. Is it written or verbal consent?

Written Verbal Not Applicable

If written please include consent form with translations. If verbal, please state in simple words (in Sinhala / Tamil / English) in a separate sheet what information you would convey to the participants and state below how consent would be documented).

Annex A

- 6.4. How will you ensure that the participant is adequately informed? Please include information sheets with translations.

- 6.5. How will you ensure your information is understood (comprehension) and queries answered?

- 6.6. Would the participants have difficulty understanding the information due to, for example, age (children under 16 or senility), illiteracy, impaired cognition due to illness/trauma?

Yes No

If YES justify the use of this group and detail the arrangement for obtaining proxy consent?

- 6.7. Are you offering any financial or other incentives/ rewards/ compensation to the research participants?

Yes No

If YES please list them and state why they do not constitute undue inducement to participate (All incentives to be provided to research participants must be approved by the ERC).

- 6.8. How will you ensure that consent is given voluntarily and not due to deception, intimidation or inducement?

- 6.9. Are the research participants under your care?

Yes No

If YES please state how you would ensure they would not feel obliged to participate in order to receive better medical care.

- 6.10. Will you obtain fresh informed consent if the procedures are changed during the research?

Yes No Not Applicable

Confidentiality

- 6.11. How will data/samples be obtained?

- 6.12. How long will data/samples be kept?

- 6.13. Are you collecting the minimum information/samples required to fulfill the study objectives?

Yes No

- 6.14. Who will have access to the personal data of the research participants?

- 6.15. How will you safeguard the privacy of the research participant?

- 6.16. What is the data/sample storage and disposal procedure in relation to ensuring confidentiality and security of personal information?

- 6.17. If you are planning to store data/samples for future study, will you obtain appropriate consent?

Yes No

Rights of the participants

6.18. How will you ensure the participants unconditional right to withdraw from the research at any time?

6.19. Outline the procedures you will provide for the research participants to ask questions and register complaints.

6.20. Who is the contact person for the research participants?

6.21. Is there provision for participants to receive information that is relevant to their participation? Explain.

Yes No Not Applicable

If Yes/NO Explain.

6.22. Is there provision for the subjects to be informed of results of clinical research? Explain.

Yes No Not Applicable

6.23. Is there provision to make the study product if any available to the study participants following the research?

Yes No Not Applicable

If Yes/NO Explain.

7. Fair participant selection

7.1. What is your study population?

7.2. Justify your choice of the study population.

7.3. Is the selection of participants (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?

Yes No Not Applicable

If YES/NO Explain.

7.4. How is the initial contact and recruitment to be conducted?

7.5. Is the research conducted on a vulnerable group?

Yes No

If YES please fill up section 9.

7.6. Is the research an externally sponsored research?

Yes No

If YES please fill up section 10.

Annex A

7.7. Is your research a community research?

Yes No

If YES please fill up section 11.

7.8. Is your research a clinical trial?

Yes No

If YES please fill up section 12.

8. Responsibilities of the researcher

8.1. What are the responsibilities of the researcher for provision of medical services to research participants?

8.2. What are the provisions for continuation of care after the research is over?

8.3. Have you followed any applicable legal regulations or other guidelines?

Yes No Not Applicable

If No Explain.

8.4. Have you obtained permission from the relevant authorities?

Yes No Not Applicable

If YES name the authorities. If NO who are you planning to get permission from?

8.5. Please declare any conflicts of interest including payments received by you or co-researchers and other rewards (Please list them and state how you would prevent them from influencing the conduct of the study).

8.6. Do you see any other ethical / legal/ social /financial issues in your study? (Please list them and state how you would prevent them from influencing conduct of the study)

8.7. I do not wish the following reviewers / ERC members to review my application.

8.8. I am willing to provide 6 monthly reports of my research to the Ethics Committee.

Yes No Not Applicable

9. Vulnerable groups (those socially disadvantaged on account of illiteracy, economic status, social status etc. and those with limited autonomy such as prisoners, service personnel etc.)

9.1. What is the justification for using the vulnerable group instead of the general population?

9.2. What is the procedure for obtaining (proxy) consent?

9.3. What is the procedure for withdrawal from research due to refusal(dissent) of research participant?

Annex A

9.4. Are you providing adequate medical and psychological support? Explain.

Yes No Not Applicable

9.5. Will the benefits of research be made reasonably available to this population? Explain.

Yes No Not Applicable

10. Externally sponsored research

10.1. Has the research project been approved by an ERC/ IRB in the sponsoring country?

Yes No

If YES, please attach documentary evidence. If NO, why?

10.2. Why is the research carried out in Sri Lanka and not in the sponsoring country?

10.3. What is the relevance of this study to Sri Lanka?

10.4. What are the post-research benefits to Sri Lanka such as availability of product, capacity building?

10.5. Are you adhering to any specific laws/ regulations/ guidelines of Sri Lanka and the sponsoring country/countries applicable to the study?

Yes Not applicable

If YES, list them.

10.6. How have you taken into account cultural and social customs, practices, and taboos in Sri Lanka when designing your study? Explain.

Yes No Not Applicable

10.7. Are participants receiving the best current treatment as part of the protocol?

Yes No

If NOT, explain why?

10.8. What is the ancillary care provided (treatment that is not part of the protocol)?

10.9. What are the provisions for continuity of care?

10.10. How will the rights to intellectual property be shared?

10.11. Are any of the data or biological samples to be transferred overseas?

Yes No

If YES, describe the fate of the data or biological samples at the conclusion of the study.

Annex A

10.12. How will the results of research be conveyed to relevant authorities in Sri Lanka?

11. Community based research

11.1. State the impact and relevance of the research on the community in which it is to be carried out.

11.2. State the steps taken to consult with the concerned community during the design of the research.

11.3. What procedures will be used to obtain community consent?

11.4. What procedures will be used to obtain individual consent?

11.5. How will you safeguard the privacy of the participants?

11.6. If the intervention is shown to be beneficial will the sponsor continue to provide it to participants after conclusion of the study? If not, explain why.

Yes No

11.7. Will the intervention or product developed or knowledge generated be made reasonably available and affordable for the benefit of the population?

Yes No

11.8. How does the research contribute to capacity building of the community?

11.9. How will the results of the research be made available to the concerned community?

12. Clinical trials

12.1. What phase clinical trial is being conducted?

- | | |
|---------------------------|--------------------------|
| Phase I | <input type="checkbox"/> |
| Phase II | <input type="checkbox"/> |
| Phase III | <input type="checkbox"/> |
| Phase IV (post marketing) | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

If OTHER specify.

12.2. Is it a multicentre trial?

Yes No

12.3. Is the clinical trial registered with a clinical trials registry?

Yes No

If YES name it.

Annex A

12.4. Have adequate animal toxicity and teratogenicity trials been carried out?

Yes No

12.5. What is the justification for using a control arm?

12.6. Does the control group receive the standard therapy?

Yes No Not Applicable

12.7. Are all participants treated equally?

Yes No Not Applicable

If NOT explain.

12.8. What is the procedure for dealing with adverse events?

12.9. What is the procedure for reporting adverse events?

12.10. Will the sponsoring agency provide the drug / device to the patient till it is marketed in the country?

Yes No

12.11. What are the criteria for termination of the trial?

12.12. Is there provision for insurance of the trial participants? Explain.

Yes No

Application for Ethics Review – Part III

for official use

Application No:

--	--	--	--	--	--	--	--	--	--

Application Checklist

I declare that I have attached the following documents (Please tick the check box and confirm):

1. Application Form: Part I

[2 copies]

2. Application Form: Part II

[2 copies]

3. The complete research proposal including the justification, objectives, and methods in detail.

[2 copies]

4. Information sheet for research participants (Should be provided in all three languages – Sinhala, Tamil, and English).

[2 copies each]

5. Consent forms (Should be provided in all three languages – Sinhala, Tamil, and English).

[2 copies each]

6. Data collection booklets/forms/questionnaires. (Should be provided in all three languages – Sinhala, Tamil, and English if self administered by research participants)

[2 copies]

7. A receipt for the appropriate payment to the accounts department.

I understand that the application for ethics clearance will not be accepted unless all documents are submitted. I declare that I am not seeking approval for a study that has already commenced or has already been completed. I understand that at least two months are required for ethics review and granting ethics clearance.

.....
Signature of Principal Investigator/Supervisor

.....
Date

Information Sheet/Consent Form

We recommend that you use the following format to assist you in preparing the information sheet/consent form. Some steps stated below may not be relevant to your study. Please select those which are applicable to your study

I am (state name of principal investigator), attached to the (state institute). My current designation is (state the designation). I would like to invite you to take part in the research study titled (state the title of the project here) conducted by (state the name of the investigator/s) at (state the site of the study here).

1. Purpose of the study

The purpose of this research is (state the expected purpose of the research here).

2. Voluntary participation

Your participation in this study is voluntary. You are free to not participate at all or to withdraw from the study at any time despite consenting to take part earlier. There will be no loss of medical care or any other available treatment for your illness or condition to which you are otherwise entitled. If you decide not to participate or withdraw from the study you may do so at any time.

3. Duration, procedures of the study and participant's responsibilities

The procedure/s to be carried out is/are (state the procedure/s of the research and how the participant has to take part in the study).

You will need to undergo the following visits and procedures (state the expected duration of participation, including the number and duration of visits to the research site and what happens at each visit).

4. Potential benefits

Participation in this study may benefit you/others by (state all the actual and potential benefits).

5. Risks, hazards and discomforts

(Any potential or actual risks, hazards and discomforts should be clearly defined)

6. Reimbursements

You would be paid a sum of Rs. (state any payment to the participant indicating the amount, when it would be paid and any conditions attached to it).

7. Confidentiality

Confidentiality of all records is guaranteed and no information by which you can be identified will be released or published. These data will never be used in such a way that you could be identified in any way in any public presentation or publication without your express permission.

8. Termination of study participation

You may withdraw your consent to participate in this study at any time, with no penalty or effect on medical care or loss of benefits. Please notify the investigator as

Annex B

soon as you decide to withdraw your consent.

9. Clarification

If you have questions about any of the tests / procedures or information please feel free to ask any of the persons listed below.

(State a list of persons with contact details from whom the participant can ask questions and clarify any doubts and their contact details).

10. To be completed

a. By the participant

The participant should complete the whole of this sheet himself/herself.

1. Have you read the information sheet? (Please keep a copy for yourself) YES/NO
2. Have you had an opportunity to discuss this study and ask any questions? YES/NO
3. Have you had satisfactory answers to all your questions? YES/NO
4. Have you received enough information about the study? YES/NO
5. Who explained the study to you?
6. Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your future medical care? YES/NO
7. Sections of your medical notes, including those held by the investigators relating to your participation in this study may be examined by other research assistants. All personal details will be treated as STRICTLY CONFIDENTIAL. Do you give your permission for these individuals to have access to your records? YES/NO
8. Have you had sufficient time to come to your decision? YES/NO
9. Do you agree to take part in this study? YES/NO

Participant's signature.....Date.....

Name (BLOCK CAPITALS).....

b. By the investigator

I have explained the study to the above volunteer and he/ she has indicated her willingness to take part.

Signature of investigator.....Date.....

Name (BLOCK CAPITALS).....

You should make the above available in all relevant languages.
Do not duplicate the above sample consent form. Use it as a guide to prepare the consent form to be used in your study.

Ethics Review Evaluation Form

for official use

Application No:

	Yes	No	NA	Comments
Is all the documentation provided?				
Scientific importance and validity				
1. Will the study lead to improvements in human health and wellbeing or increase knowledge?				
2. If the study is a replication of a previous study, is it justified?				
3. Can the intervention studied be practically implemented?				
4. Is there provision for dissemination of results of the research?				
5. Has the research protocol been approved by a competent body?				
6. Should the study be referred to a technical expert, policy maker or statistical expert?				
If YES, please inform the Secretary/ERC as soon as possible, suggesting a suitable person.				
If NOT,				
7. Are the objectives stated clearly?				
8. Is the study design appropriate in relation to the objectives?				
9. Is the study designed using accepted principles, methods and practices?				
10. Is there a plausible data analysis plan?				
11. Do the sample size and statistical techniques have adequate power to produce reliable and valid results using the smallest number of research participants?				
12. Are the investigators qualifications, competence and experience appropriate to conduct the study?				
13. Are the facilities at the site adequate to support the study?				
14. Is the manner in which the results of research will be reported and published ethical?				
Assessment of Risks/Benefits				
1. Is the involvement of human participants necessary to obtain the necessary information?				
2. Are the researcher qualifications, competence, and experience suitable to ensure safe conduct of the study?				
3. How safe is the intervention to be used in the research?				

Annex C

	Yes	No	NA	Comments
4. Is the justification of predictable risks and inconveniences weighted against the anticipated benefits for the research participant and the concerned communities adequately?				
5. Are there any plans to withdraw or withhold standard therapy for the purpose of research and such actions if any justified?				
6. Is the standard of care the best available locally?				
7. Is the medical and psychological support for the participants adequate?				
8. Is the site including support staff, facilities and emergency procedures adequate?				
9. Is there provision for compensation for participants who sustain injuries?				
10. Have adequate provisions been made for dealing with and reporting adverse effects?				
11. Have adequate provisions been made for safety monitoring and termination of the research project?				
12. Is there a possibility of an intervention being available to the population if found effective?				
Respect for the dignity of the research participants				
<i>Informed consent</i>				
1. Is the process for obtaining informed consent appropriate?				
2. Are the participants competent?				
3. Is the justification for the intention to include individuals who cannot consent adequate?				
4. Are the arrangements for obtaining proxy consent for such individuals appropriate?				
5. Will dissent be respected?				
6. Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable?				
7. Do you approve the incentives offered?				
8. Is the consent given voluntarily and not due to deception, intimidation or inducement?				
9. Will fresh informed consent be obtained if the procedures are changed during the research?				
10. Is there an opportunity for the participant to ask questions regarding the research?				
<i>Confidentiality</i>				
1. Will the researcher collect only the minimum information/samples required to fulfill the study objectives?				

Annex C

	Yes	No	NA	Comments
2. Is the privacy of the research participant safeguarded?				
3. Are data/sample storage and disposal procedures adequate?				
<i>Rights of the participants</i>				
1. Is the participant's right to unconditionally withdraw from the research at anytime safeguarded?				
2. Is there provision for the participants to ask questions and register complaint?				
3. Is there provision for participants to be informed about newly discovered risks or benefits during the study?				
4. Is there provision for the subjects to be informed of results of clinical research?				
5. Is there provision to make the study product available to the participants following research?				
Fair participant selection				
1. Has the study population been determined, primarily, based on the scientific goals of the study (and not on convenience, ethnicity, age, gender, literacy, culture or economic status)?				
2. Is the selection of participants (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?				
3. Does the selection of participants stigmatize any group?				
4. Does selection of subjects favour any group?				
5. Is the initial contact and recruitment appropriate?				
6. Is the research conducted on vulnerable individuals or groups?				
7. Is the research externally sponsored?				
8. Is the research a community research?				
9. Is the research a clinical trial?				
Responsibilities of the researcher				
1. Is the medical care to be provided to the research participants during and after the research adequate?				
2. Has the researcher followed any applicable legal regulations or other guidelines?				
3. Has the researcher obtained permission from the relevant authorities?				
4. Are there any conflicts of interest, including payments and other rewards?				

Annex C

	Yes	No	NA	Comments
5. Are there any other ethical / legal/ social /financial issues in the study?				
Vulnerable group				
1. Can the research be equally well carried out in another, less vulnerable, group?				
2. Will the study result in new knowledge relevant to the health needs of this population?				
3. Is the procedure for obtaining (proxy) consent adequate?				
4. Will the subject's withdrawal from research due to refusal (dissent) be always upheld?				
5. Is there a favourable risk benefit ratio?				
6. Is the medical and psychological support adequate?				
7. Will the benefit of the research be made reasonably available to this group?				
Externally sponsored research				
1. Is there a local collaborator?				
2. Has the research project been approved by a ERC/ IRB in the sponsoring country?				
3. Is the justification for the research to be carried out in Sri Lanka and not in the sponsoring country adequate?				
4. Is the research relevant to Sri Lanka?				
5. Are the post-research benefits to the country acceptable?				
6. Are relevant local laws/ regulations/ guidelines of each country adhered to?				
7. Is the research responsive to cultural/social differences?				
8. Are participants receiving the best current treatment as part of the protocol?				
9. Is the ancillary care provided adequate?				
10. Are the provisions for continuity of care adequate?				
11. Are the provisions for intellectual property sharing fair?				
12. If the data/biological samples are to be transferred overseas, is there adequate provision to safeguard the interests of the subjects and protect intellectual property rights?				
13. Is there provision for results of research to be conveyed to relevant authorities in Sri Lanka?				
14. Are any conflicts of interest resolved?				
15. Is there a written agreement between the collaborators?				

Annex C

	Yes	No	NA	Comments
Community based research				
1. Is the impact and relevance of the research on the community in which it is to be carried out acceptable?				
2. Has the concerned community been consulted during the design of the study?				
3. Is community consent obtained?				
4. Is individual consent obtained?				
5. Is the privacy of the participants safeguarded?				
6. If the intervention is shown to be beneficial will the sponsor continue to provide it to participants after conclusion of the study?				
7. Will the intervention or product developed or knowledge generated be made reasonably available and affordable for the benefit of the population?				
8. Does the research contribute to capacity building of the community?				
9. Will the results of the research be made available to the concerned community?				
10. Are any conflicts of interest resolved?				
Clinical trials				
1. If it is a multicentre trial, are all centres following the same protocol?				
2. Is the clinical trial registered with a clinical trials registry?				
3. Have adequate animal toxicity and teratogenicity trials been carried out?				
4. Is their sufficient justification for using a control arm?				
5. Does the control group receive the standard therapy?				
6. Are all subject participants treated equally?				
7. Is the procedure for dealing with adverse events adequate?				
8. Is the procedure for reporting adverse events adequate?				
9. Will the sponsoring agency provide the drug / device to the patient till it is marketed in the country?				
10. Are the criteria for termination of the trial detailed?				
11. Is there provision for insurance of trial participants?				

Annex C

Additional Comments:

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

Recommendation: Approve *Reject* *Conditional Approval (please state the conditions)*

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

Name of Reviewer:

Signature:

Date:/...../.....

Participants and Contributors

**Participants at the National Conference On “Responding To Emerging Ethical Issues In Research On Human Subjects: Working Towards A National Consensus”
30 November to 2 December 2006 at the Faculty of Medicine, University of Colombo.**

Resource Persons

Prof. Reidar Lie – *Senior Research Fellow, Department of Clinical Bioethics, National Institute of Health, Bethesda, Maryland, USA*

Dr. Vasantha Muthuswamy – *Senior Deputy Director General & Chief, Division of Basic Medical Sciences, Indian Council of Medical Research, New Delhi, India.*

Prof. Nalaka Mendis – *Professor of Psychological Medicine, and Chairperson, Ethics Review Committee, Faculty of Medicine, Colombo.*

[Chairperson, Organising Committee]

Dr. Vajira H.W. Dissanayake – *Senior Lecturer in Anatomy/Genetics, and Secretary, Ethics Review Committee, Faculty of Medicine, Colombo.*

[Secretary, Organising Committee]

Dr. Enoka Corea – *Senior Lecturer in Microbiology; Member, Ethics Review Committee, Faculty of Medicine, Colombo; Member, Ethics Committee, Sri Lanka Medical Association.*

[Person in charge of the Capacity Building Workshop]

Prof. Rohini Fernandopulle – *Professor in Pharmacology, and Member, Ethics Review Committee, Faculty of Medicine, Colombo.*

[Person in charge of the National Consensus Workshop]

Dr. Malik Fernando – *Member, Ethics Review Committee, Colombo; Member, Ethics Review Committee, Sri Lanka Medical Association; Member, National Bioethics Committee, National Science Foundation; Chairman, Ethics Committee, Sri Lanka Medical Association.*

[Person in charge of the Uniform Guidelines Workshop]

Annex D

Participants

Faculty of Medicine, University of Colombo

Members of the ERC

- Prof. Manouri Senanayake – *Professor in Paediatrics*
Prof. Mandika Wijeratne – *Professor in Surgery*
Mrs. Kantha Lankathilake – *Senior Lecturer in Community Medicine*
Dr. Ariyarani Gnanadasan – *Senior Lecturer in Clinical Medicine*
Dr. Shamila Jayasena – *Senior Lecturer in Biochemistry*

Academic Faculty Members

- Dr. Nilakshi Samaranyake – *Lecturer in Parasitology*
Dr. Nilukshi Abeyasinghe – *Senior Lecturer in Forensic Medicine*
Dr. Prabha Mallawarachchi – *Lecturer in Anatomy/Genetics*
Dr. Nalika Gunawardena – *Senior Lecturer in Community Medicine*
Dr. Ajith Malalasekara – *Senior Lecturer in Anatomy*
Dr. Mangala Gunathilaka – *Senior Lecturer in Physiology*
Dr. Ushani Rajapakse – *Lecturer in Microbiology*

Sri Lanka Medical Association

- Prof. Anoja Fernando – *Chairperson/ERC*
Dr. Janani Pinidiya Pathirage – *Secretary/ERC*
Dr. P. Mark S. Perera – *Member/ERC*

Faculty of Medicine, University of Ruhuna

- Prof. Susirith Mendis – *Professor of Physiology*
Dr. Saman Wimalasundara – *Senior Lecturer*
Dr. Ajith De S. Nagahawatta – *Senior Lecturer*

Faculty of Medicine, University of Kelaniya

- Prof. Asitha de Silva – *Professor of Pharmacology*
Dr. A. Pathmaswaran – *Senior Lecturer in Parasitology*
Dr. C.D. Ranasingha – *Senior Lecturer in Pharmacology*

Annex D

Dr. Pushpa Jayawardena – *Senior Lecturer in Family Medicine*

Dr. Sunil Fernando – *Senior Lecturer in Obstetrics and Gynaecology*

Dr. Sureka Chakrawarthy – *Senior Lecturer in Biochemistry*

Faculty of Medical Sciences, University of Sri Jayewardenepura

Dr. Renu Wickramasinghe – *Senior Lecturer in Parasitology*

Dr. Chamara Senaratne – *Senior Lecturer in Community Medicine*

Faculty of Health Care Sciences, Eastern University of Sri Lanka

Prof. T. Varugunam – *Vice Chancellor*

Dr. K.E. Karunakaran – *Dean*

Dr. T. Sathaanathan – *Senior Lecturer*

Faculty of Medical and Allied Health Sciences, Rajarata University

Prof. Malkanthi Chandrasekara – *Dean*

Prof. Thilak Weerasuriya – *Professor of Anatomy*

Dr. P.T.R. Makuluoluwa – *Senior Lecturer in Physiology*

Medical Research Institute, Colombo

Dr. Lulu Raschid – *Director*

Dr. J. Munasinghe – *Consultant Clinical Pharmacologist*

Dr. M.M Gunathilaka – *Consultant Chemical Pathologist*

Dr. Mayuri Thammitiyagoda – *Veterinary Surgeon*

Dr. Sepali Gunawardene – *Consultant Immunologist*

Mr. R. Ramesh – *Research Officer*

National Hospital of Sri Lanka, Colombo

Dr. Rani Fernando – *Deputy Director*

Castle Street Hospital for Women, Colombo

Dr. W. Karandegoda – *Director*

Dr. G.A. Ranatunga – *Consultant Obstetrician & Gynaecologist*

Dr. P.G. Senthilnathan – *Consultant Obstetrician & Gynaecologist*

Dr. Hasthuka Ellaepola – *Senior Registrar in Obstetrics & Gynaecology*

Annex D

Dr. Anoja Jayasekara – *Registered Medical Officer*

Dr. Chandrani Gunasekara – *Senior Medical Officer*

De Soysa Hospital for Women, Colombo

Dr. Roy Perera – *Director*

Eye Hospital, Colombo

Dr. S. Yoganathan – *Director*

Dr. K.D. Jayalath – *Deputy Director*

Dr. Champa Banagala – *Consultant Ophthalmologist*

Dr. Charith Fonseka – *Consultant Ophthalmologist*

Dr. Mangala Gamage – *Consultant Ophthalmologist*

Dr. P.A. Senanayake – *Consultant Immunologist*

Teaching Hospital, Kurunegala

Dr. S.P.A. Hewage – *Judicial Medical Officer*

Other Ethics Review Committees that were invited but could not participate in the conference

Faculty of Medicine, University of Peradeniya

Faculty of Dental Sciences, University of Peradeniya

Prof. Lilani Ekanayake – *Chairperson, Research, Ethical and Higher Degrees Committee could not participate; but made written representations on behalf of her committee.*

Faculty of Medicine, University of Jaffna

Lady Ridgeway Hospital for Children

Sri Jayewardenepura General Hospital

In response to invitation for comments, following the circulation of the draft guidelines to editors of indexed journals published in Sri Lanka and medical professional collages and associations, written comments were received from:

Prof. Colvin Goonaratne, Joint Editor, Ceylon Medical Journal

Prof. Laal Jayakody, Co-editor, Sri Lanka Journal of Medical Sciences

College of Community Physicians

Annex D

Other members of the Ethics Review Committee and other academic of the Faculty of Medicine, Colombo who contributed were:

Prof. Kamani H. Tennakoon – *Professor of Physiology/Director, Institute of Biochemistry, Molecular Biology, and Biotechnology*

Dr. Priyadarshani Galappaththy – *Senior Lecturer in Pharmacology*

Dr. Hemantha Senanayake – *Senior Lecturer in Obstetrics and Gynaecology*

Dr. Suriyakanthi Beneragama – *Consultant Epidemiologist*

Prof. Rohan W. Jayasekara – *Professor of Anatomy/Director, Human Genetics Unit*

Participants at the ERCSL Workshops

Workshop on Biological Samples and Human Genetic Data: Collection, Processing, Use and Storage

23 June 2007 at the Faculty of Medicine, University of Colombo

ERC, Sri Lanka Medical Association

Prof. Anoja Fernando

Dr. Malik Fernando

ERC, Faculty of Medicine, University of Colombo

Dr. Vajira H.W. Dissanayake

Prof. Kamani H. Tennakoon

Dr. Enoka Corea

Dr. Malik Fernando

Dr. Ariyarani Gnanadasan

Dr. Suriyakanthi Benaragama

Dr. Sharmila Jayasena

Ms. Agra Rajapakse

Faculty of Medicine, University of Jaffna

Dr. T. Chenthuran

ERC, Faculty of Medical Sciences, University of Sri Jayewardenepura

Dr. Renu Wickremasinghe

Annex D

Dr. Chamara Senaratne

ERC, Medical Faculty, University of Kelaniya

Dr. Sureka Chackrewarthy

ERC, Faculty of Medicine, University of Ruhuna

Dr. Ajith De S. Nagahawatta

ERC, National Hospital of Sri Lanka

Dr. Rani Fernando

Dr. Shirani Hapuarachchi

Dr. A. Ileperuma

ERC, Sri Jayewardenepura General Hospital

Dr. A. S. Rodrigo

ERC, Lady Ridgeway Hospital for Children

Dr. H.M.S. Vidyatilake

Dr. S. Yoganathan

Workshop on International Collaborative Research

24 June 2007 at the Faculty of Medicine, University of Colombo

ERC, Sri Lanka Medical Association

Prof. Anoja Fernando

Dr. Udaya Ranawake

Dr. Malik Fernando

ERC, Faculty of Medicine, University of Colombo

Dr. Vajira H.W. Dissanayake

Dr. Enoka Corea

Mrs. Kantha Lanakatilake

Dr. Malik Fernando

Dr. Priyadarshani Galappaththi

Annex D

Dr. Ariyarani Gnanadasan

Dr. Sharmila Jayasena

Ms. Agra Rajapakse

Faculty of Medicine, University of Jaffna

Dr. T. Chenthuran

ERC, Faculty of Medical Sciences, University of Sri Jayewardenepura

Mr. W.S.S. Pathmasiri

Mrs. V.G.N.S. Velathanthri

Mr. M.A. Siriwardena

ERC, Faculty of Medicine, University of Ruhuna

Dr. Ajith de S. Nagahawatta

Dr. A.T.I. M. Jayawardena

ERC, National Hospital of Sri Lanka

Dr. Rani Fernando

ERC, Sri Jayewardenepura General Hospital

Dr. A. S. Rodrigo

ERC, Lady Ridgeway Hospital for Children

Dr. S. Yoganathan

ISBN 978-955-1747-00-8