ETHICS REVIEW COMMITTEE GUIDELINES

A FERCSL Operational Guidance for Committees that Review Biomedical Research Proposals

Forum for Ethics Review Committees in Sri Lanka
FERCSL
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Ethics Review Committee Guidelines
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Introduction to 2nd Edition

Research is essential for gathering new knowledge and for the advancement of science. Research ethics strives to ensure protection of research participants, thereby enhancing the quality of research. While many international guidelines on research ethics have been developed and disseminated, the key to success is the application of these universal principles in a local setting. An essential component of such research ethics guidelines is the need for such research to be subject to prior review by a competent Ethics Review Committee (ERC).

The initial publication of "ERC guidelines - A Guide for Developing Standard Operating Procedures for Committees that Review Biomedical Research Proposals" was produced by the Forum for Ethics Review Committees in Sri Lanka (FERCSL) in 2007 to promote the use of uniform standard operating procedures by ethics review committees (ERCs) that review biomedical research proposals involving human participants, tissue and data. Since then there has been a significant increase in the number of ERCs in Sri Lanka and the need for uniform standards to be maintained in the ethics review process has been keenly felt. New areas in research have emerged and with them, new ethical issues have surfaced. The revision of the guidelines was undertaken in this background.

The document being revised was divided in to sections and each section was perused by designated member ERCs of the Forum for Ethics Review Committees in Sri Lanka (FERCSL). The changes suggested were discussed by all member ERCs of FERCSL and the final document was circulated to all member ERCs for observations. This document has been produced after incorporating the changes that have been agreed upon.

The revised document of 2018 has been re-named "A FEFCSL

Operational guidance for Committees that Review Biomedical Research Proposals". It is designed to provide guidance to ERCs throughout Sri Lanka to enable them to develop their own procedures to suit the administrative structure of their parent organisations, yet conform in essential details and content to internationally accepted standards. It is hoped that this would lead to a uniform approach in assessing ethical aspects of research proposals.

Professor Chandanie Wanigatunge
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Dr Malik Fernando

Colombo, Sri Lanka 2018

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Abbreviations

CV : Curriculum Vitae
ERC : Ethical Review Committee
SOP : Standard Operating Procedures
TOR : Terms of Reference
WHO : World Health Organisation

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1. The Role of Ethics Review Committees

The Ethics Review Committee (ERC) is a committee established to review the ethics of research involving human subjects including 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 wellbeing of all 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 principles as stated in the Declaration of Helsinki. The tasks of the ERC should be executed free of bias and influence.
The ERC has the authority to request research protocol modifications, enforce and monitor all informed consent or participants/animal rights issues and to suspend or stop any research that doesn't conform to the protocol approved by the ERC.

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 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 (refer 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 from those eligible to submit applications to the ERC. Those eligible should be identified by the ERC/Institution.
1.1.2. Provide independent review of biomedical research
1.1.3. Be available to researchers for consultation on ethical

issues;

1.1.4. Develop standard operating procedures (SOP) for ethics review and ethical conduct of research in the medical and other related fields, within the limits of national/international guidelines;

1.1.5. 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;

1.1.6. Educate and train ethics review committee members to ensure the quality and consistency of ethics review;

1.1.7. Liaise with other ERC in matters of common interest;

1.1.8. Advise, support and facilitate the work of other ethics review committees on ethics issues;

1.1.9. Inform relevant government agencies of matters that may have policy implications that come to their notice during ethics review;

1.1.9.1. Promote community awareness and consult with individuals, communities and government on ethics issues relating to research on human subjects;

1.1.9.2. Keep abreast with international developments in relation to ethical issues and liaise with relevant international organisations and individuals.

1.2. Scientific Value and Validity of a Research Proposal

Any proposed research should be scientifically sound if it is to be ethically acceptable. It is ideal to have a scientific review committee review a proposal for scientific validity prior to ethical review. 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 (refer 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.

2.2.2. Terms and conditions of appointment

2.2.2.1. Appointments should be made for a limited term (e.g. 3 years) with provision for re-appointment. A rotational system for replacement of existing members should be considered to allow for continuity, the development and maintenance of expertise within the ERC, and the regular input of fresh ideas and approaches.

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

2.2.4. Procedure for initial orientation and continuing training. The initial orientation and training requirements and continuing education of ERC members should be specified.

2.3. Composition

ERC should be multidisciplinary, multisectoral, and pluralistic. Heads of institutions/ Appointing Authority should not be members as it could adversely affect the independence of ERC.

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 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:

2.3.2. Two to three persons with expertise in basic medical sciences, including statistics;

2.3.3. Two to three clinicians;

2.3.4. A person with knowledge of ethics of medical research;

2.3.5. A person with expertise in law;

2.3.6. A person with expertise in philosophy/social science;

2.3.7. A person with expertise in public health research/ statistics;

2.3.8. A lay person conversant with social values.

2.3.9. A chairperson and a secretary should be elected by the members and be appointed by the institution or other Appointing Authority. The duties and responsibilities of each post should be clearly stated in the SOP.

2.3.9.1. The quorum for meetings should be laid down together with its composition, e.g. 'at least one lay member', etc. (refer 4.3).

2.3.9.2. 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.

2.3.9.3. Whenever there is a possibility of conflict of interest members should declare their association with the proposal and withdraw from the deliberations (refer 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.

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3. Ethics Review

3.1. General Considerations

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 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. 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 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 categories.

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, vaccine or, 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 (refer 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 too.

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 (refer 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 (refer 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.

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.

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. Ethical 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.

3.3.2.2.

a. A local collaborator (co-investigator) from Sri Lanka with equal responsibility is essential.
b. A Memorandum of understanding 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 Out of Sri Lanka should be in accordance with existing national 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 in the proposal.

f. A Material Transfer Agreement should be drawn between the Researcher and those receiving and processing the samples. This should clearly state what the samples would be used for, the duration of sample storage and the ultimate fate of the sample. (Annex A, B, C). This agreement should be submitted to and approved.

3.3.2.3. 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.

3.3.2.4. If the research is sponsored by an external organisation, the research protocol, when applicable, 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 (refer 3.3.5), the permission of their guardians or legally authorized persons.

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 (The WHO information sheets can be obtained from http://www.who.int/rpc/research_ethics/informed_consent/en/).

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) (refer link on 3.3.3.1), 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:

3.3.3.4.1. convey the information in a language and manner that is appropriate to the individual's level of understanding; and

3.3.3.4.2. give the participant ample opportunity to ask questions and respond to them honestly, promptly and completely

3.3.3.4.3. 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;

3.3.3.4.4. ensure that the participant understands that consent is being sought for research and that it may or may not include clinical care;

3.3.3.4.5. ensure that the participant understands that he/she is free to withdraw consent at any time without fear of consequences;

3.3.3.4.6. refrain from deception, undue

influence, inducement or coercion

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 (refer 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.

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

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

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.

- Consent for research involving children below the age of 18 years should be obtained from their parents or guardians.
- 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 (refer 3.3.9).
- However, it is best to involve the child, whenever possible (depending on the age and degree of maturity), when obtaining such assent.
- 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 or Legally Authorized Representative.

- 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 or Legally Authorized Representative.
- 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:
The equity 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 Underprivileged or marginalized groups or communities, 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 assent 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 despite parent's/ guardian's consent;

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 (refer 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 foetus 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 foetuses 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 at least two members (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.
b. The task of the principal reviewer would be facilitated by using an evaluation form that should be developed by the ERC.

4.1.2. It would be helpful if the principal reviewer could ask for clarifications in case of deficiencies, in the application, from 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 – refer 4.5) and a decision made as to whether the proposal
- Proposal is scientifically sound
- 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 (refer 6.3).

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

4.1.4.3. If the application is rejected, reasons should be given (refer 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 be such that sufficient time is 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 an elected member if the chairperson is absent), and 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 advice 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 (refer 2.3).

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. 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. 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.

4.5.2. 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.

4.5.3. 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.

4.5.4. 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 (refer 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 (refer 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. In the absence of a separate committee to review scientific validity the ERC should perform this task.

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 should be of value to either science or society or to both. 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 of value, the treatment, intervention or theory will have to improve health and wellbeing 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.

However the ERC may adopt special considerations when reviewing undergraduate research.

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

5.2. Scientific Validity

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. the research has a clear scientific objective;

5.2.2. the research is designed

5.2.2.1. using accepted principles, methods, and reliable practices;

5.2.2.2. to meet the stated objectives of the study

5.2.3. the research has sufficient power to definitively test the objective with the smallest number of research participants;

5.2.4. a plausible data analysis plan is provided; and

5.2.5. the researcher / research team 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.

5.3.1.3. whether participants are selected purely based on scientific principles and not included or excluded due to convenience

5.3.1.4. whether participants have been left out

merely for convenience.

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 (refer 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 regular medical practitioner if any, when appropriate, including the procedure for seeking the participant's consent to do so;

5.5.1.7. evidence that consent is truly voluntary and not due to deception, undue influence, inducement or intimidation; and

5.5.1.8. evidence that participants are informed that they are free to withdraw consent at any time without fear of consequences.

5.5.1.9. evidence that participants are informed that their tissue samples will be stored for future studies and nature of such studies (if applicable)

5.5.1.10. the process for obtaining informed consent from the next of kin when using organs and tissues from cadavers;

5.6. Respect for Potential and Enrolled Participants and Communities

Research participants should have their privacy protected and their wellbeing 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 wellbeing); 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 (refer 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. This interval would be determined by the ERC based on the proposal.

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.

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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.

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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. Registry of Projects submitted
- 9.2.4. Applications to ERC
  - 9.2.4.1. one copy of all material submitted by applicants;
  - 9.2.4.2. correspondence by ERC members with applicants or concerned parties regarding applications, decisions, and follow-up;
  - 9.2.4.3. a copy of the decisions and any advice or requirements sent to applicants;
  - 9.2.4.4. all correspondence and other material received during the follow-up;
- 9.2.5. ERC membership;
  - 9.2.5.1. CV of the member
  - 9.2.5.2. appointment letter as the member of ERC
  - 9.2.5.3. Confidentiality and conflict of interest agreement
  - 9.2.5.4. Certificates: attending or conducting workshops or training related to Ethics Review
  - 9.2.5.5. Other correspondents to and from the member
- 9.2.6. ERC standard operating procedures (SOP) and Terms of Reference (TOR);
  - 9.2.6.1. Copy of all versions of SOP and TOR
- 9.2.7. Financial records
  - 9.2.7.1. Records on income and expenditure
  - 9.2.7.2. Annual financial report
- 9.2.8. Annual reports.

9.2.8.1. Projects reviewed and their current status
9.2.8.2. Nominations and appointments
9.2.8.3. Workshops and training (conducted/ attended)
9.2.8.4. Revision and amendments to SOP and TOR
9.2.8.5. Summary of income and expenditure for the year

9.2.9. Other correspondents
9.2.9.1. Workshops, Conferences, etc.
9.2.9.2. Ministry and other regulatory bodies

10. References

1. International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva. Council for International Organizations of Medical Sciences (CIOMS); 2016.
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. 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: 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.

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11. Contributors

The document was circulated among the following member ERCs of FERCSL and views were obtained. These were discussed and the final document was compiled.

1. Ethics Review Committee, Faculty of Medicine, Colombo.
2. Ethics Review Committee, Faculty of Medical Sciences, University of Sri Jayewardenepura
3. Ethics Review Committee, Faculty of Medicine, Jaffna.
4. Ethics Review Committee, Faculty of Medicine, Peradeniya
5. Ethics Review Committee, Faculty of Medicine, Rajarata
6. Ethics Review Committee, Faculty of Medicine, Sir John Kothalawala Defence University.
7. Ethics Review Committee, Faculty of Applied Sciences, Rajarata
8. Ethics Review Committee, Faculty of Medicine, Kelaniya.
9. Ethics Review Committee, Sri Lanka Medical Association.
10. Ethics Review Committee, College of Paediatricians.
11. Ethics Review Committee, Institute of Indigenous Medicine
12. Ethics Review Committee, Teaching Hospital Kurunegala.
13. Ethics Review Committee, National Institute of Mental Health

A subcommittee nominated by the Management committee of the FERCSL compiled the final document

1. Professor Chandanie Wanigatunge
2. Dr Shamini Prathapan
3. Dr Malik Fernando
4. Professor A Pathmeswaren
5. Dr Sampath Tennakoon

The following members edited the final document

1. Professor Chandanie Wanigatunge
2. Dr Shamini Prathapan
3. Dr Malik Fernando

Annex A: Material Transfer Agreements (MTA)

General Introduction

An MTA can be drawn up in two scenarios:

1. Where a Sri Lankan scientist sends biological material abroad to a recipient scientist, institution or laboratory for the purpose of analysis, the results to be transmitted to the requesting scientist for publication or other purpose (research paper, diagnosis, clinical therapy etc.)
2. Where a scientist abroad requests a Sri Lankan scientist for biological specimens from Sri Lanka for the purpose of conducting research, the results to be published by him.

In either case the Agreement should be:

a) Between two Institutions;
b) The PROVIDER and the RECIPIENT of the biological material should be clearly identified by INSTITUTION and NAME of scientist;
c) The nature of the MATERIAL should be clearly described, and any accompanying data relating to the MATERIAL that accompanies it should be considered CONFIDENTIAL INFORMATION and be a part of the MATERIAL.
d) The PURPOSE for which the material is transferred should be clearly described;
e) The fate of the RESULTS should be clearly stated;
f) The OWNERSHIP of the material and the RESULTS should be clearly stated as well as PUBLISHING RIGHTS;
g) The FATE OF MATERIAL REMAINING should be clearly stated:
   (i) return to PROVIDER or
   (ii) destroy in an appropriate, previously agreed or described, manner;
h) RESTRICTIONS on sharing the MATERIAL and CONFIDENTIAL INFORMATION and any derived products, prohibitions on commercial and other use such as on humans and for therapy shall be explicitly stated;
i) The PERIOD OF VALIDITY of the agreement shall be clearly stated as well as the mechanism for prior termination of the agreement.

   Two templates have been drafted: MTA-1 to be used in scenario 1 and MTA-2 to be used in scenario 2.

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Annex B: FERCSL Template for Material Transfer Agreement (MTA-1)

For Transfer of Material for analysis and report

In response to the RECIPIENT agreeing to receive the MATERIAL & CONFIDENTIAL INFORMATION [insert description] _____ the PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives the MATERIAL:

1. The above MATERIAL is the property of the PROVIDER and is made available for the PURPOSE as described hereunder: [insert PURPOSE]
2. The MATERIAL is to be used for the stated PURPOSE only. The RECIPIENT will only use the MATERIAL and CONFIDENTIAL INFORMATION to conduct work in vitro or in laboratory animals, as necessary for the PURPOSE, and will not modify the MATERIAL. The RECIPIENT will not use the MATERIAL or CONFIDENTIAL INFORMATION in any other way, including in humans or for commercial purposes.
3. The RECIPIENT is to only provide the MATERIAL and disclose the CONFIDENTIAL INFORMATION to employees or students who need to know the same for the PURPOSE and the RECIPIENT shall be responsible for ensuring that all such persons comply with this Agreement.
4. The RECIPIENT agrees to notify the PROVIDER of the Results, data and any discoveries that arise from the RECIPIENT's use of the MATERIAL and CONFIDENTIAL INFORMATION, as requested under PURPOSE.
5. The RECIPIENT agrees to return to the PROVIDER / destroy (strike out inapplicable) any unused MATERIAL and all CONFIDENTIAL INFORMATION upon the completion of the PURPOSE.
6. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The PROVIDER makes no representations and extends no Warranties of any kind, either expressed or implied. There are no express or implied

Warranties of merchantability or fitness for a particular purpose, or that the use of the material will not infringe any patent, copyright, trademark, or other proprietary Rights. Unless prohibited by law, RECIPIENT assumes all liability for claims for damages against it by third parties which may arise from the use, storage or disposal of the MATERIAL except that, to the extent permitted by law, the PROVIDER shall be liable to the RECIPIENT when the damage is caused by the gross negligence or wilful misconduct of the PROVIDER.

7. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations.
8. The period of validity of this Agreement shall be _____ months (insert period) from the date of execution.
9. This Agreement may only be changed in writing signed by both parties.
10. The provisions of this Agreement are separate and severable. If a provision of this Agreement is void or voidable or unenforceable because of illegality or other reason then, it shall be severed from this Agreement which will otherwise remain in full force and effect.
11. All notices, requests and other communications between the PROVIDER and the RECIPIENT shall be in writing, shall be addressed to the contact person identified in the Agreement or the relevant scientist, and if sent by airmail shall be deemed received one week after the day of mailing.

The PROVIDER, RECIPIENT and RECIPIENT SCIENTIST must sign both copies of this Agreement and return one signed copy to the PROVIDER. The PROVIDER will then send the MATERIAL.

Provider information and authorized signature
Provider Scientist:
_____
Provider Organization:
_____
Address: _____
e-mail:_____
Contact person if different from above:
_____

Name of Authorized Official:

_____

Title of Authorized Official:

_____

_____

Signature of Authorized Official / Date

Recipient information and authorized signature
Recipient Scientist:

_____

Recipient Organization:

_____

Address: _____
e-mail:_____
Contact person if different from above:

_____

Name of Authorized Official:

_____

Title of Authorized Official:

_____

_____ _____

Signature of Authorized Official / Date

Certification of Recipient Scientist: I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the MATERIAL.

_____ _____

Recipient Scientist / Date

Note: 'Authorized Official' refers to Institution official authorized to sign Material Transfer Agreements on behalf of the Institution.

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Annex C: FERCSL Template for Material Transfer Agreement (MTA-2)

For Transfer of Material at the Request of a Scientist outside the Provider's Institution

In response to the RECIPIENT's request for the MATERIAL & CONFIDENTIAL INFORMATION described as follows [insert description] _____ the PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives the MATERIAL:

1. The above MATERIAL is the property of the PROVIDER and is made available for the PURPOSE as described hereunder: [insert PURPOSE] _____
2. The MATERIAL is to be used for the stated PURPOSE only. The RECIPIENT will only use the MATERIAL and CONFIDENTIAL INFORMATION to conduct work in vitro or in laboratory animals, as necessary for the PURPOSE, and will not modify the MATERIAL. The RECIPIENT will not use the MATERIAL or CONFIDENTIAL INFORMATION in any other way, including in humans or for commercial purposes.
3. The RECIPIENT is to only provide the MATERIAL and disclose the CONFIDENTIAL INFORMATION to employees or students who need to know the same for the PURPOSE and the RECIPIENT shall be responsible for ensuring that all such persons comply with this Agreement.
4. The MATERIAL will not be further distributed to others without the PROVIDER's written consent. The RECIPIENT shall refer any request for the MATERIAL to the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agree to make the MATERIAL available, under a separate Agreement to other scientists for teaching or not-for-profit research purposes only.
5. The RECIPIENT agrees to acknowledge the source of the MATERIAL in any publications reporting use of it.
6. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The PROVIDER makes no representations and extends no Warranties of any kind, either

expressed or implied. There are no express or implied Warranties of merchantability or fitness for a particular purpose, or that the use of the MATERIAL will not infringe any patent, copyright, trademark, or other proprietary Rights. Unless prohibited by law, RECIPIENT assumes all liability for claims for damages against it by third parties which may arise from the use, storage or disposal of the MATERIAL except that, to the extent permitted by law, the PROVIDER shall be liable to the RECIPIENT when the damage is caused by the gross negligence or wilful misconduct of the PROVIDER.

7. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations.
8. The MATERIAL is provided at no cost, or with an optional transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs. If a fee is requested, the amount will be indicated here: [insert fee]_____.
9. The period of validity of this Agreement shall be _____ months (insert period) from the date of execution.
10. This Agreement may only be changed in writing signed by both parties.
11. The provisions of this Agreement are separate and severable. If a provision of this Agreement is void or voidable or unenforceable because of illegality or other reason then, it shall be severed from this Agreement which will otherwise remain in full force and effect.

12. All notices, requests and other communications between the PROVIDER and the RECIPIENT shall be in writing, shall be addressed to the contact person identified in the Agreement or the relevant scientist, and if sent by airmail shall be deemed received one week after the day of mailing.

The PROVIDER, RECIPIENT and RECIPIENT SCIENTIST must sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER will then send the MATERIAL.

Provider information and authorized signature
Provider Scientist:

_____

Provider Organization:

_____

Address: _____

e-mail:_____

Contact person if different from above:

_____

Name of Authorized Official:

_____

Title of Authorized Official:

_____

_____ _____

Signature of Authorized Official / Date

Recipient information and authorized signature

Recipient Scientist:

_____

Recipient Organization:

_____

Address: _____

e-mail:_____

Contact person if different from above:

_____

Name of Authorized Official:

_____

Title of Authorized Official:

_____

_____ _____

Signature of Authorized Official / Date

Certification of Recipient Scientist: I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the MATERIAL.

_____ _____

Recipient Scientist / Date

Note: 'Authorized Official' refers to Institution official authorized to sign Material Transfer Agreements on behalf of the Institution.

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Annex D: Informed Consent forms

Instructions

Informed consent form should have two parts
Part 1: information sheet
Part 11: certificate of consent
Please use the templates below (pages 2 & 4) to assist you in preparing the information sheet and consent form. Do not duplicate the sample information sheet. Some paragraphs may not be relevant to your study. Please select those which are applicable to your study. Use the template as a guide to prepare the Information Sheet to be used in your study, paying particular attention to the wording when the information is directed at parents and guardians of minors less than 18 years of age, who will constitute the study population.
The Consent Form template may be used in its entirety for most studies needing consent from adults. However, in the case of proxy consent, the sentences will need to be suitably re-worded. An extra statement is needed if tissue samples are to be stored
It is a good idea if provision is made for sufficiently mature children to give their assent, in addition to the parental consent. In this case, there needs to be a separate form for the child's assent in addition to the form for parental proxy consent with a suitable heading.
You should make the forms available in English, Sinhala and Tamil. However, you may limit to English and one of the other languages, or English alone, if you can justify the exclusion of any language/s on the basis of the language competence of the study population.
All forms – as well as all other documents submitted for review – should contain page numbers as well as the version number and date in the page header.

Part 1: Information Sheet

<Heading: State the title of the research project here>
Introduction
I…….. (Name of the PI) attached to……..(state Institute) as…….. (designation) would like to invite you to take part in the….(title of the research) conducted by ……. (names of investigator/s) at (site of study)

a. Purpose of study
   Explain the purpose of study (in simple / lay terms)

b. Type of research intervention
Explain what type of intervention that will be undertaken

c. Participation selection
State why this participant has been chosen for this research

d. Voluntary participation
Clearly indicate that each individual can choose to participate or not to participate

e. Procedure and protocol
Describe or explain the procedure that will be followed on a step by step. Explain what you expected them to do. Write "we would like to ask you to …….". Explain what is routine and what is experimental

f. If it is a clinical trial - provide information on the trial drug (name). Which phase of the trial. Why you compare or test this new drug. Explain known information /experience of the trial drug

g. If any samples (blood/sputum/biopsy ….) taken
Explain when/how many times/any preparations needed/what will be done with them/how long they will be stored/ how these are discarded/do they be sent abroad.

h. Duration
Indicate a statement about the time commitment (research duration and follow up)

i. Risks
Explain any possible /anticipated risks. If any problem occurs what will be the action

j. Benefits
Mention actual benefits. (not what they are entitled due to participate in the research)
Mention is it individual or community benefit

k. Reimbursement
State clearly what you will provide for their participation. Ex travel cost/money for wages lost

l. Confidentiality
Explain how the research team will maintain the confidentiality of data

m. Sharing of results
Mention plan of sharing results

n. Right to refuse or withdraw
Mention that participation is voluntary and has right to withdraw/refuse at any stage without explaining why? It will not affect the individual's right to get proper / routine / treatment / care

o. Whom to contact
Contact numbers of PI and other investigators. Mention who gave approval for this and the contact number of that ERC

Part 11: Consent Form

<Heading: State the title of the research project here>
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

< If tissue samples are to be stored for later studies, insert an additional section here as no. 10. Asking for agreement
(a) to store tissue;
(b) to use stored material for future research
(i) into the same condition as present research,
(ii) research into any condition. >

Participant's
signature……..……Date……..
Name (BLOCK CAPITALS)……

b. By the investigator

I have explained the study to the above participant and he/she has indicated willingness to take part.
Signature of investigator……..……..Date……..
Name (BLOCK CAPITALS)……

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