



ERC-NATA

**Ethics Review Committee of the National Authority on
Tobacco and Alcohol**

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PREFACE

The National Authority on Tobacco and Alcohol (NATA) was established under section 2 of the National Authority on Tobacco and Alcohol Act, No 27th of 2006, with the responsibility to reduce tobacco and alcohol-related harm through public health policy development and implementation, and advocacy. The authority is functioned under five key objectives as,

- To identify the broad and specific policies in relation to tobacco and alcohol (and other narcotics) for protecting public health
- To eliminate tobacco and alcohol related harm through the assessment and monitoring of the production, marketing, advertising and consumption of tobacco products and alcohol products
- To make provisions discouraging persons especially children from smoking or consuming alcohol by curtailing their access to tobacco products and alcohol products
- To promote and adopt and implement clean air laws and restrict the availability spaces to protect the community from tobacco and alcohol
- To propose and promote all other measures, including cessation of tobacco and alcohol programmes necessary to prevent harm from tobacco and alcohol to the population.

The Ethics Review Committee (ERC) of the National Authority on Tobacco and Alcohol (ERCNATA) was established in 2021 to provide ethics reviews for tobacco and alcohol control-related research projects involving humans. The ERCNATA helps the researchers in promoting and adhering to ethical principles in research, including obtaining ethics clearance for the research projects. In addition, the ERCNATA serves as a monitoring body, monitoring and suppressing attempts by the tobacco and alcohol industries to disseminate inaccurate and misleading information through research.

MESSAGE FROM THE CHAIRMAN



National Authority on Tobacco and Alcohol (NATA) is the pioneer government institution that was established under the National Authority on Tobacco and Alcohol Act no 27th of 2006 with the purpose of enactment of the legal aspects of tobacco and alcohol control in Sri Lanka. Even after a year of its emergence, COVID 19 was a great barrier that has impeded the projects of the National Authority on Tobacco and Alcohol. But the authority managed to put several plans into action and successfully revitalized the campaign against tobacco consumption and alcoholism.

With reference to the Global Tobacco Industry Interference of 2021, it is evident that the grip of the industry on Sri Lanka has only tightened. The tobacco and alcohol industries have capitalized on the opportunities opened up amidst the COVID crisis, extending its reach to many vulnerable demographics. There is plenty of evidence of tobacco and alcohol industry interferences in many forms. One of the prevailing methods that they are continuously practicing is spreading misleading and false information as scientific research articles. These unauthentic research projects should be suppressed. Because that false information covers the real harm of these deadly substances, it leads the public to continue the consumption and influences the decisions of public health policymakers.

As the chairman of NATA, I strongly believe that research projects conducted locally on tobacco and alcohol should be closely monitored to limit the industry influences. On the other hand, other researchers will benefit from this type of monitoring mechanism since they will be able to undertake tobacco and alcohol control-related research more successfully and also obtain support from NATA whenever necessary. NATA, as the country's leading policy-making agency for tobacco and alcohol control, is always eager to encourage genuine researchers to conduct studies in this field and contribute to the control of these deadly substances.

The Ethics Review Committee of the National Authority on Tobacco and Alcohol (ERCNATA) was established in 2021, with the aim of monitoring and encouraging authentic research projects on tobacco and, alcohol control. ERCNATA provides ethics reviews for tobacco and alcohol control-related research projects involving humans. The ERCNATA helps the researchers in promoting and adhering to ethical principles in research, including obtaining ethical clearance for the research projects. In addition, the ERCNATA serves as a monitoring body, monitoring

and suppressing attempts by the tobacco and alcohol industries to disseminate inaccurate and misleading information through research. At the ERCNATA, we have gathered the eminent professionals covering a vast area and I'm sure that their potential is more than expected. Further, I'm happy that ERCNATA is recognized by the Ministry of Health as an approved committee to grant ethical clearance for the research projects. We are planning to acquire the recognition for the ERCNATA from the Forum for Ethics Review Committees of Sri Lanka (FERCSL) as well.

I urge all the interested researchers in Sri Lanka especially young researchers to get involved with ERCNATA and publish their research on our national recognized platforms. In 2021, NATA introduced the National Symposium on Tobacco and Alcohol (NSTAP) as a national level research-oriented platform aiming to enrich the literature in tobacco and alcohol-related research conducted in Sri Lankan setting and provide inspiration to the researchers to contribute to enriching the tobacco and alcohol control-related scientific evidence. Continuing this initiative, NATA has established a scientific journal to publish research articles related to tobacco and alcohol control in 2022.

As common issues need common solutions, both the Ethics Review Committee of NATA and the National Symposium on Tobacco and Alcohol Prevention (NSTAP) provide a valuable opportunity to the tobacco and alcohol control community at the national level. NATA believes that we are the connectors at the national level which can connect and empower stakeholders including researchers who are committed to tobacco and alcohol control in the country.

NATA works with great dedication to eradicate smoking and dismantle the influence of alcohol in society. NATA approaches a smoke-free Sri Lanka where alcohol is a redundant commodity. It promises years of innovation and new mechanisms that boast and work towards a brighter future.

Dr. Samadhi W. Rajapaksa

Chairman

National Authority on Tobacco and Alcohol

ETHICS REVIEW COMMITTEE OF THE NATIONAL AUTHORITY ON TOBACCO AND ALCOHOL



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Additional Secretary
Ministry of Mass Media



Secretary

Mr. Viraj Bandaranayake
Legal Officer - NATA



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Board member of NATA



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Faculty of Dental Sciences
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Prof. Chandani Liyanage
Faculty of Art
University of Colombo



Prof. C.S. Weeraratne
Former professor in Rajarata
University of Sri Lanka &
University of Ruhuna



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Faculty of Medicine
University of Jaffna



Prof. Kusumalatha
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Faculty of Allied Health
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GUIDELINES OF THE ETHICS REVIEW COMMITTEE OF NATIONAL AUTHORITY ON TOBACCO AND ALCOHOL

1. INTRODUCTION

National Authority on Tobacco and Alcohol (NATA) is the pioneer government institution which was established under the National Authority on Tobacco and Alcohol Act no .27th of 2006 with the purpose of enactment of the legal aspects of tobacco and alcohol control in Sri Lanka.

These guidelines have been formulated to adhere to the use of standard operating procedures by Ethics Review committee of the National Authority on Tobacco and Alcohol (ERCNATA) that reviews research proposals that include biomedical, sociological, psychosocial, economic and clinical research involving human participants in research in tobacco and alcohol related aspects in Sri Lanka.

Further these guidelines ensure that participants are exposed to minimal risks in relation to any potential benefits that might result from the research.

2. OBJECTIVES

- 2.1 Protect the mental and physical welfare, rights, dignity and safety of human participants in research
- 2.2 Facilitate ethical research by effective and efficient review and monitoring processes.
- 2.3 Review research in accordance with national and/or local regulations
- 2.4 Identify broad and specific measures in relation to tobacco and alcohol control
- 2.5 Monitor and evaluate the implementation and enactment of measures in relation to tobacco and alcohol control
- 2.6 Promote evidence based biomedical, sociological, psychosocial, economic and clinical research on tobacco and alcohol for upgrading the cessation and prevention of those substance to ensure safety and rights of research participants, researchers and general public
- 2.7 To evaluate areas on potential conflict of interest and bring out research work with genuine interest for the public

3. INSTITUTIONAL RESPONSIBILITY AND STATUS OF ERCNATA

- 3.1 Institutions have a responsibility to respect the autonomy of ERCNATA.

3.2 The ERCNATA is an advisory committee of the National Authority on Tobacco and Alcohol, with responsibility for:

- granting ethical approval;
- withholding ethical approval;
- withdrawing ethical approval for research to be carried out in accordance with relevant National and International Guidelines and Laws.

3.3 The Chairman is responsible for granting the institutional approval for research to be conducted giving due consideration to the advice of the ERCNATA. The Chairman of the NATA shall not give institutional approval for research to be conducted within the Institute unless ethical approval has been granted by the ERCNATA and a letter to that effect has been issued by the Chairperson of the ERCNATA.

3.4 The Chairman and the Board of Directors of the NATA has delegated to the ERCNATA to give approval on behalf of the NATA to conduct of ethically approved research.

- approve amendments on behalf of the NATA to research
- monitor research on behalf of the NATA
- Encourage and assist research on issues related to tobacco and alcohol control
- Conduct, promote, and coordinate research in related to tobacco and alcohol control
- Suspend approval on behalf of the NATA for the conduct of research
- Withdraw approval on behalf of the NATA for the conduct of research

Note: As a formality ERCNATA decisions will be submitted to the Board of Directors-NATA for record in NATA board minutes ERC shall keep autonomy for their decisions.

3.5 ERC Office and human resource

3.5.1 Institute should create and maintain an ERCNATA office with adequate support systems to enable to function of ERCNATA with office staff and infrastructure facilities

3.5.2 ERCNATA office staff shall;

- Coordinate and process all initial, continuing review, and study modification submissions.
- Compose letters to researchers, relaying specific ERCNATA requests and follow-up.
- Compose ERCNATA meeting minutes.

- Coordinate electronic distribution of applications and related documents received for review.
- Coordinate and process all ERCNATA Adverse Event Reporting (i.e. on-site/off-site Adverse Events).
- Maintain the electronic database of the ERCNATA.
- Perform any other duties assigned by the Chairperson and Secretary.

4. MEMBERSHIP

4.1 Composition

- 4.1.1 The composition of ERCNATA should be in accordance with the relevant international and national guidelines of forum of ethics review committees
- 4.1.2 ERCNATA should consist of following members
 - I. Chairperson (a member from the ERCNATA with the knowledge of tobacco and alcohol related research ethics)
 - II. Secretary (shall be the Board secretary of NATA)
 - III. Five experts from medical field including Ayurveda medicine with the knowledge of tobacco and alcohol related research ethics
 - IV. Two experts from community medicine with the knowledge of tobacco and alcohol related research ethics
 - V. One expert from respiratory diseases with the knowledge of tobacco and alcohol related research ethics
 - VI. One expert from social science with the knowledge of tobacco and alcohol related research ethics
 - VII. One expert from economic field with the knowledge of tobacco and alcohol related research ethics
 - VIII. One expert from pediatric medicine field with the knowledge of tobacco and alcohol related research ethics
 - IX. One expert from oncological medicine field with the knowledge of tobacco and alcohol related research ethics
 - X. One expert from psychiatry field with the knowledge of tobacco and alcohol related research ethics
 - XI. One legal expert
 - XII. One expert with knowledge of Statistics

- XIII. One expert with philosophy background
 - XIV. One expert from human behavioral study field
 - XV. Four persons representing the lay communities
 - XVI. One expert with knowledge of agriculture and environmental sciences
 - XVII. One expert with knowledge of pharmacology
- 4.1.3 A quorum must be present in order for the ERCNATA to reach a final decision on any agenda item. A quorum shall exist when at least eight (8) members of which at least one member is a lay member is present. In circumstances where members cannot be present, they may provide written comments in lieu of attendance. However, in these circumstances, there must be at least eight (8) members physically present to achieve quorum, including one lay member.
- 4.1.4 The ERCNATA shall be free to consult any person(s) considered by the ERCNATA to be qualified to provide advice and assistance in the review of any research proposal submitted to it, subject to that person(s) having no conflict of interest and providing an undertaking of confidentiality. Such person(s) shall not be entitled to vote on any matter.
- 4.1.5 Handling of conflicts of interest:
- 4.1.5.1 At the ERCNATA meetings member should inform the Chairperson if he/she has a conflict of interest, financial or otherwise, in a proposal or other related matter(s) to be considered by the ERCNATA.
 - 4.1.5.2 The ERCNATA will determine if this results in a conflict of interest for the member and, if so the member will withdraw from the present meeting until the ERC's consideration of the relevant matter has been completed. The member shall not be permitted to adjudicate on relevant research.
 - 4.1.5.3 All declarations of conflict of interest and the absence of the member concerned will be recorded in minutes.

4.2 Appointment

- 4.2.1 The chairperson and the secretary will be nominated by the ERCNATA, from among its members who representing the NATA, and the names submitted to the Board of Directors. Upon approval by Board of Directors, the Chairperson of the board of directors will issue the letters of appointment.
- 4.2.2 On the recommendation of ERCNATA other members will be appointed by the Board of Directors of NATA. Upon approval by the Board of Directors of NATA, the Chairman of NATA will issue the letters of appointment.

- 4.2.3 The Board of Directors shall reserve the right to terminate them on reasonable grounds during their tenure of office upon the recommendation of ERCNATA.
- 4.2.4 Members of the ERCNATA may be recruited by direct approach, nomination or by advertisement.
- 4.2.5 Members are appointed in their individual capacity and not by designation.

4.3 Terms and Conditions of appointment

- 4.3.1 The membership shall hold office for a period of three (3) years from the date of appointment and shall, unless remove from office be eligible for reappointment
- 4.3.2 Any appointed member who fails to attend 3 consecutive meetings without prior approval from the ERCNATA shall be deemed to have vacated his office as a member unless exceptional circumstances exist. The chairperson will notify the member in writing of such lapse of membership and steps to taken to fill the vacancy
- 4.3.3 A member can resign from the ERCNATA at any time by giving notice in writing to the Chairperson. Upon receipt of such notice, steps shall be taken to fill the vacancy of a prospective member.
- 4.3.4 Inform by the ERCNATA the Chairman may terminate the appointment of any member of the ERCNATA if they are of the opinion that: - it is necessary for the proper and effective functioning of the ERCNATA; - the person is not a fit and proper person to serve on an ERCNATA; - the person has failed to carry out his/her duties as an ERCNATA member.
- 4.3.5 Members will be provided with a letter of appointment which will include date of appointment, length of tenure, and TOR.
- 4.3.6 Throughout the tenure, members will be provided the opportunity to attend conferences and workshops relevant to the work and responsibilities of the ERCNATA at the expense of the ERCNATA.
- 4.3.7 Members must agree to their names and professions being made publicly available, including being published on the committee's website.
- 4.3.8 Payment to the committee members for sitting at a time, payment to the secretary for summarizing the projects reports and for other documentation work, and payment to the visiting expert who is adequately qualified to provide advice and assistance for reviewing the research project proposal will be decided by the board of directors of NATA
- 4.3.9 Members shall be required to sign a statement undertaking: - that all matters of which he/she becomes aware during the course of his/her work on the ERCNATA shall be kept confidential; - that any conflicts of interest which exist or may arise during his/her tenure on the ERCNATA shall be declared; and - that he/she has not

been subject to any criminal conviction or disciplinary action which may prejudice his/her standing as a ERCNATA member.

5. ACCOUNTABILITY OF ERCNATA

- 5.1 The ERCNATA is accountable to the Board of Directors of the NATA in the conduct of its duties. The minutes of each ERCNATA meeting shall be forwarded to the Board of Directors of the NATA.
- 5.2 The ERCNATA shall provide an annual report to the Chairman and the Board of Directors at the end of each calendar year.
- 5.3 The ERCNATA may from time to time bring to the attention of the Chairman and the Board of Directors of NATA issues of significant concern.
- 5.4 The ERCNATA Terms of Reference, Standard Operating Procedures (SOPs) and membership shall be available upon request to the general public and shall be posted on the website.

6. CONDUCT OF BUSINESS/CODE OF CONDUCT

6.1 Procedures

- 6.1.1 The ERCNATA shall perform its functions according to written SOPs. These procedures shall be reviewed at least every two years and amended and updated as necessary. All ERCNATA members shall have access to and/or be provided with copies of the procedures and shall be consulted with regard to any proposed changes.

6.2 Submissions, notifications, and approvals

- 6.2.1 All applications for ethical approval must be submitted to the ERCNATA, on or before next ERCNATA proceedings, in writing in the format approved from time to time by the ERCNATA and shall include such documentations as the ERCNATA may specify
- 6.2.2 Guidelines shall be issued to assist applicants in the preparation of their applications
- 6.2.3 The ERCNATA may request the applicant to supply further information in relation to an application and/or request the applicant to attend a meeting of the ERCNATA at which the application shall be considered for the purpose of providing information to and answering questions from the ERCNATA members
- 6.2.4 The ERCNATA shall consider every correctly completed application which it receives at its next available meeting following receipt, provided that the application

is received on time. The Secretary shall circulate the completed application and associated documents received with a meeting agenda to all members of the ERCNATA at least five (5) days prior to the next meeting

- 6.2.5 The ERCNATA may delegate consideration of certain scientific/technical matters to an ERCNATA member. The ERCNATA may also obtain expert scientific/technical advice, subject to paragraph 4.1.5.
- 6.2.6 The ERCNATA may take into account the opinions or decisions of another ethics review committee in relation to a research protocol.
- 6.2.7 Following its review, the ERCNATA shall promptly notify the applicant in writing, advising whether the application has received ethical approval and any conditions of that approval. If the ERCNATA has granted approval, it shall inform the applicant in writing that the research may commence. Notification of the ERCNATA decisions shall normally be sent within five (5) working days
- 6.2.8 The ERCNATA may receive and review progress reports and project completion reports.

6.3 Expedited review

- 6.3.1 The ERCNATA may establish an Executive, consisting of at least the Chairperson (or nominee), Secretary (or nominee) and an officer of the ERCNATA. In accordance with the Standard Operating Procedures, the Executive may undertake expedited review of research proposals between scheduled meetings at the discretion of the Chairperson. The Executive may seek advice from other ERCNATA members, as appropriate, before reaching a decision. If approval is granted, such approval shall be considered for ratification at the next ERCNATA meeting
- 6.3.2 The Executive may consider other items of business that are considered to be of minimal risk to participants such as expected non serious adverse events, protocol reports, minor amendments and the like. The minutes of any such meetings shall be tabled for ratification at the next ERCNATA meeting.

6.4 Multi-center research

- 6.4.1 To facilitate multi-center research the ERCNATA may: - communicate with any other ERC; accept a scientific/technical and/or ethical assessment of the research by another ERC.

6.5 Research involving children

Permission of the parents or guardians should be obtained when research is conducted using children. In this case, the child means a person under the age of 18 years. If a child refuses to participate in research his refusal should be accepted. If parents/guardian request to withdraw

from the research while the research is in progress they should be allowed. The researcher should bear in mind that the “best interest of the child” concept is safeguarded. Any research involving children should be reviewed with extra attention and should be extra cautious whether the child face stigma or discrimination as a result of the research.

6.6 Research involving pregnant women

All pregnant mothers should be clearly and adequately informed about the possible risks and benefits to their physical and mental health, pregnancy and the fetus due to the project. It is the responsibility of the researcher to inform the ERCNATA if there are reliable evidence of case studies regarding risk of teratogenicity and mutagenicity.

6.7 Advocated and interpreters

- 6.7.1 The ERCNATA shall consider whether an advocate for any participant or group of participants should be invited to the ERCNATA meeting to ensure informed decision- making.
- 6.7.2 Where research involves the participation of persons unfamiliar with the English language, the ERCNATA shall ensure that the participant information sheet and the informed consent form is translated into the participant’s language and /or that an interpreter is present during the discussion on the project.

6.8 Conducting meetings

- 6.8.1. Meetings of committee shall normally be held at approximately monthly intervals or more frequently as necessary.
- 6.8.2. Meeting dates and agenda closing dates shall be published appropriately.
- 6.8.3. In order to be considered at a scheduled meeting, items for discussion and other correspondence shall normally be received at the ERCNATA office by the first day of the month.
- 6.8.4. Other issues may be tabled and considered at a scheduled meeting with the approval of the Chairman.
- 6.8.5. Committee member involved in an issue under consideration shall absent him/ herself from the meeting during the discussion.
- 6.8.6. The Committee shall reach decisions by consensus after all members have been given the opportunity to express their views. In the event that a consensus cannot be reached, a decision may be taken by voting (show of hands). A simple majority shall normally be required for a decision to be made. Dissenting views shall be recorded in the minutes.

- 6.8.7. The committee may make recommendations and/or prepare discussion papers/ reports for consideration by the ERCNATA, the Director, or any other person or organization considered appropriate by the Committee.

7. FEES

- 7.1.1 A fee shall be charged for applications and amendments submitted for assessment by the ERCNATA.
- 7.1.2 The applicable fees shall be determined from time to time and announced in advance by the ERCNATA.

8. RECORDS

- 8.1 The secretary and/or a designated official of the ERCNATA shall prepare and maintain written records of the ERCNATA activities, including agendas and minutes of all meetings of the ERCNATA.
- 8.2 The secretary and/or a designated official of the ERCNATA shall prepare and maintain a file for each application received including a copy of the application, and any relevant correspondence including that between the applicant and the ERCNATA.
- 8.3 Files shall be kept securely and confidentially, and retention should be electronically archived
- 8.4 Records shall be held for sufficient time to allow for future reference. The minimum period for retention is at least five years from the date of completion of a project but for specific types of research, such as clinical trials, 15 years shall apply. Files which are no longer required for retention shall be electronically archived.
- 8.5 The ERCNATA shall maintain a register of all the applications received and reviewed in accordance with the Guidelines of the Forum of Ethics Review Committees in Sri Lanka and other relevant national and international guidelines.

9. POST-APPROVAL RESPONSIBILITIES

- 9.1 The ERCNATA shall monitor approved projects for compliance with the ERCNATA ethical approval. In doing so, the ERCNATA may request and discuss information on any relevant aspects of the project with the investigators at any time. In particular, the ERCNATA shall require investigators to provide a report at least 6 monthly, and at completion of the study.
- 9.2 The ERCNATA shall, as a condition of approval of each project, require that investigators immediately report anything which might warrant review of the ethical approval of the project, including:

- Proposed changes in the research protocol or conduct; - unforeseen events that might affect continued ethical acceptability of the project;
 - serious unexpected adverse reactions occurring in participants at sites monitored by the ERCNATA and other adverse events as decided by the ERCNATA, in accordance with relevant guidelines
 - If the project is abandoned for any reason
- 9.3 The ERCNATA may adopt any additional appropriate mechanism for monitoring as deemed necessary

10. COMPLAINTS AND REVIEW

10.1 Complaints concerning the conduct of a project

- 10.1.1.1 Any concern or complaint about the conduct of a project should be directed to the attention of the person nominated by the ERCNATA. The person nominated by the ERCNATA to receive complaints shall notify the Chairperson as soon as possible after a complaint is received. The Chairperson and the secretary of the ERCNATA shall investigate the complaint and make a recommendation on the appropriate course of action. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Director or his/her nominee or request the Chairperson to do so.

10.2 Complaints concerning the ERCNATA review process

- 10.2.1 Any complaint about the ERCNATA review process should be directed to the Chairperson of the ERCNATA. Complaints may also be made to the Chairman. The Chairperson shall notify the Chairman of any complaints received by him/her, as soon as possible. The Chairman shall inform the Chairperson of any complaints received by him/her as soon as possible. The Chairperson shall investigate the complaint and its validity and make a recommendation to the ERCNATA on the appropriate course of action. If the complainant is not satisfied with the outcome of the Chairperson's investigation, then he/she can refer the complaint to the Chairman, or his/her nominee, or request the Chairperson to do so. The Chairperson shall provide to the Chairman all relevant information about the complaint/concern. The Chairman shall determine whether there is to be a further investigation of the complaint. If it is decided that there is to be a further investigation, then the Chairman shall convene a suitable panel to review the complaint, ensuring that both the complainant and the ERCNATA are afforded the opportunity to make submissions.
- 10.2.2 In conducting its review, the panel shall be concerned with ascertaining whether the ERCNATA acted in accordance with the relevant Guidelines of the Forum

of Ethics Review Committees in Sri Lanka, its Terms of Reference, its Standard Operating Procedures, or otherwise acted in an unfair or biased manner

10.3 Appeals concerning the ERCNATA rejection of an application

- 10.3.1 A person with a complaint about the ERCNATA rejection of his/her application should bring the complaint to the attention of the Chairperson of the ERCNATA, detailing the grounds of the complaint. Complaints may also be made to the Chairman. The Chairperson shall notify the Chairman of the complaint as soon as possible. The Chairman shall notify the Chairperson of any complaints received by him/her as soon as possible. The Chairperson shall investigate the complaint and its validity and make a recommendation to the ERCNATA on the appropriate course of action at its next meeting. At the Chairperson's discretion, the complainant may be invited to attend the next ERCNATA meeting, or the complainant may request the opportunity to attend. The complainant shall be informed of the ERCNATA response in writing, normally within seven (7) working days of the ERCNATA meeting. If the complainant is not satisfied with the action taken by the ERCNATA, then he/she can refer the complaint to the Chairman, or his/her nominee, or request the Chairperson to do so. The Chairperson shall provide to the Chairman all relevant information about the complaint. The Chairman shall determine whether there is to be a further investigation of the complaint. If it is decided that there is a case to be investigated, then the chairman shall convene a suitable panel to review the complaint, ensuring that both the complainant and the ERCNATA are afforded the opportunity to make submissions. The outcomes of this process may include:
- The complaint/concern is dismissed.
 - The complaint/concern is referred back to the ERCNATA for consideration, bearing in mind the findings of the panel.
 - The application may be referred for external review by an independent ERCNATA if the Chairman concludes that due process has not been followed by the ERCNATA in reaching its decision. Should the ERCNATA be requested to review its decision, then the outcome of this review by the ERCNATA shall be final. In accordance with rules, the panel or the Chairman cannot substitute its approval for the approval of the ERCNATA.

11. REVIEW / AMENDMENT OF TERMS OF REFERENCE

- 11.1 The ERCNATA shall review the Terms of Reference annually and propose changes to the Chairman for approval if appropriate.
- 11.2 Members of the ERCNATA may from time to time propose changes to the Terms of Reference for review by the ERCNATA. If considered acceptable, such changes shall be forwarded to the Chairman for approval if appropriate.

12. ELEMENTS OF THE REVIEW PROCESS

[Ref: Forum of Ethics Review Committees- Sri Lanka, (FERCSL), 2007]

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 ERCNATA 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:

12.1 Social or Scientific Value

- 12.1.1 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 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.
- 12.1.2 The ERCNATA should ensure that there is a plan whereby results of scientific value would be disseminated.

12.2 Scientific Validity

- 12.2.1 To be ethically acceptable, research must be conducted in a methodologically rigorous manner. Scientifically unsound research in human participants unethical, in that it may expose participants to risks or inconvenience to no purpose. The ERCNATA should ensure that:
 - 12.2.1.1 The research has a clear scientific objective;
 - 12.2.1.2 The research is designed using accepted principles, methods, and reliable practices;
 - 12.2.1.3 The research has sufficient power to definitively test the objective with the smallest number of research participants;
 - 12.2.1.4 A plausible data analysis plan is provided; and

- 12.2.1.5 The researcher possesses the necessary qualifications, experience and access to facilities to carry out the proposed study.

12.3 Fair participant Selection

- 12.3.1 The recruitment protocol should ensure fair participant selection. Selection of participants should be carried out so that stigmatized 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 favored for potential research benefits. The following should be considered:
 - 12.3.1.1 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
 - 12.3.1.2 Whether the inclusion and exclusion criteria have been selected to minimize risks and maximize benefits to individual research participants and society.

12.4 Favorable Risk/Benefits Ratio

- 12.4.1 Within the context of standard clinical practice and research protocol, risks must be minimized, potential benefits enhanced and the potential benefits to the individuals and knowledge gained for society must outweigh risk. The following should be considered:
 - 12.4.1.1.1 Justification of predictable risk and inconvenience weighed against the anticipated benefits for the research participants and the concerned communities;
 - 12.4.1.1.2 Justification for the use of control arms;
 - 12.4.1.1.3 Criteria for prematurely withdrawing research participants;
 - 12.4.1.1.4 Criteria for suspending or terminating the research as a whole;
 - 12.4.1.1.5 Adequacy of provisions made for monitoring and auditing the conduct of the research including safety monitoring;
 - 12.4.1.1.6 The adequacy of the site, including the support staff, available facilities and emergency procedures;
 - 12.4.1.1.7 The suitability of the investigator's qualifications and experience for the proposed study;
 - 12.4.1.1.8 Any plans to withdraw or withhold standard therapies for the purpose of the research and the justification for such action;
 - 12.4.1.1.9 Evidence of the safety of any intervention or therapy;

- 12.4.1.1.10 The medical care to be provided to research participants during and after the course of the research;
- 12.4.1.1.11 The adequacy of medical supervision and psycho-social support for the research participants;
- 12.4.1.1.12 Steps to be taken if research participants voluntarily withdraw during the course of the research;
- 12.4.1.1.13 A description of any financial costs to research participants;
- 12.4.1.1.14 Provision for compensation and/or treatment in the case of injury, disability or death of a research participant attributable to participation in the research;
- 12.4.1.1.15 The insurance and indemnity arrangements where applicable; and
- 12.4.1.1.16 Access to any products (drugs or devise) shown to be beneficial after conclusion of the study

12.5 Informed Consent process

- 12.5.1 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. The following should be considered:
 - 12.5.1.1 The process for obtaining informed consent including the identification of those responsible for obtaining consent;
 - 12.5.1.2 The adequacy, completeness, and clarity of written and oral information to be given to the research participants and, when appropriate, their representative(s);
 - 12.5.1.3 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;
 - 12.5.1.4 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);
 - 12.5.1.5 Provision made for receiving and responding to queries and complaints from research participants or their representatives during the course of research;
 - 12.5.1.6 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;
 - 12.5.1.7 Evidence that consent is truly voluntary and not due to deception, undue influence, inducement or intimidation; and

- 12.5.1.8 Evidence that participants are informed that they are free to withdraw consent at any time without fear of consequences.

12.6 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.

12.6.1 For individuals:

- 12.6.1.1 A full description of people who will have access to personal data of the research participants
- 12.6.1.2 The measures proposed to ensure confidentiality and security of personal information concerning participants;
- 12.6.1.3 A description of any plans to make the study product available to the research participants
- 12.6.1.4 The measures taken to inform research participants about information available during the course of research, which is relevant to their participation (including their rights, safety, and wellbeing); and
- 12.6.1.5 The measures proposed to inform participants of study results when appropriate.

12.6.2 For committees:

- 12.6.2.1 The impact and relevance of the research on the wider local community and on the specific communities from which the research participants are drawn;
- 12.6.2.2 The steps taken to consult with the communities during the course of designing the research;
- 12.6.2.3 The influence of the community on the consent of individuals and proposed community consultation during the course of the research;
- 12.6.2.4 The extent to which the researcher contributes to capacity building such as the enhancement of local health care, research and the ability to respond to public health needs;
- 12.6.2.5 A description of the availability and affordability of any successful study product to the communities following the research; and
- 12.6.2.6 The measures proposed to inform the community of study results when appropriate.

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