National Guidelines for the Establishment and Functioning of Ethical Review Committees in Health Care Institutions in Sri Lanka

Education, Training & Research Unit
Ministry of Health
In collaboration with
College of Medical Administrators – Sri Lanka
2013

Education, Training & Research Unit
Ministry of Health

Vision

To enhance the Quality and Quantity of
Qualified Health Manpower
contributing to Economic, Social,
Mental and Spiritual development of Sri Lanka

Mission

To be the focal point of facilitation,
central agency of monitoring and evaluation and
principal provider of technical expertise
in Education, Training and Research spheres
in the Sri Lankan health sector
for the development of Knowledgeable,
Skilful, Efficient, Effective, Patient-Centred and
Innovative Health Staff Members

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Table of Contents

Message from Secretary of Health

Research has always been a cornerstone of development as evident by the many developed countries of the world. Therefore research will be an imperative consideration in the current and rapid development process in Sri Lanka. It has been duly mentioned in the present government's "Mahinda Chinthana – Vision for the Future" document, that conduct of research will be one of the main pathways in achieving the vision of "Wonder in Asia" and "Knowledge Hub in Asia".

Therefore, research in the health sector has a tremendous potential and scope in the future as a method of acquiring evidence-based decisions in clinical, preventive and health managerial settings. It is essential to ensure the conduct of ethically viable and technically sound research especially in the health sector, which mostly involves humans as the study participants and the Ethical Review Committees will play an invaluable role in achieving this challenging task.

This document which has been produced by the Education, Training and Research Unit of Ministry of Health, is expected to give this timely and important guidance for Ethical Review Committees established within the health care institutions of Sri Lanka. I would like to express my gratitude to Dr. Sunil De Alwis (DDG – Education, Training and Research) and his team who were involved in preparing these guidelines, on behalf of the Ministry of Health.

Dr. Y.D. Nihal Jayathillake
Secretary
Ministry of Health

Message from Director General of Health Services

Research has an important and valuable contribution in relation to the health sector development in any country. In Sri Lanka, the introduction of the payment of a research allowance and the rapid development process after the culmination of the North and East war has tremendously catalysed the quantity of research conducted in every sector including health. But to ensure the quality of the research conducted, it is essential to incorporate ethical review processes and this is a prime consideration in health research due to the involvement of humans as research subjects.

There are several reasons why it is important to adhere to ethical norms in research. These are to promote the aims of research, to promote the values that are essential to collaborative work, to be accountable to the public and to promote a variety of other important moral and social values.

Therefore, this is an invaluable attempt to develop these national guidelines for the establishment and functioning of Ethical Review Committees in health care institutions in Sri Lanka, which will ensure the above aspects in health research conduction. I most sincerely expect that all health care institutions will benefit from this document and facilitate their research and ethics review processes accordingly. I express my gratitude on behalf of the Department of Health Services, to Dr. Sunil De Alwis for taking this initiative and preparing this valuable document and extend my thanks for all those who contributed to make this endeavour a success.

Dr. P.G. Mahipala
Director General of Health Services

Preface to the National Guidelines for the establishment and functioning of Ethical Review Committees in health care institutions in Sri Lanka

Research in Sri Lanka has received special attention by the Ministry of Health and more recently by the government. The provision and applicability of quality healthcare to our people depend on locally relevant research carried out by the health staff of our institutions. The importance of the need for a sustained research culture has been recognized and priority areas of research identified. Without this, the progress and development of the health sector would be stifled. The Education, Training and Research Unit of the Ministry of Health has initiated the process of re-organizing and strengthening the processes in order to improve the quality of the product. With this aim, we have drafted the essentials of a national guideline for the establishment and functioning of Ethical Review Committees and draft guidelines for the assessment of research projects submitted to these Ethical Review Committees.

The objectives of these guidelines are to promote, coordinate and facilitate the conduction of health research and to regulate the expanding research culture within a robust ethical and scientific framework in the Sri Lankan health sector. This will also aim to improve the utilization of the findings of conducted research for locally relevant and appropriate evidence based decisions and for the betterment of the country. Therefore, we firmly believe that this booklet would be a useful tool in achieving good quality research from the health sector.

We gratefully acknowledge the Forum of Ethics Review Committees, Sri Lanka, the Ethics Review Committee – Faculty of Medicine – University of Colombo, Sri Lanka Medical Association the Institute of Research and Development and the College of Medical Administrators for the contributions, guidelines and formats that are used herein.

Dr. Sunil De Alwis
Deputy Director General -
Education, Training and Research

Background

Health research is an impérative part in the ever changing, continuously modernising and rapidly evolving health system, as they provide updated and evidence-based knowledge for all health care decision makers either in clinical or non-clinical fields. Therefore, health research has made an important contribution to health development since its early days. The Deputy Director General – Education, Training and Research Unit (DDG-ET&R) of Ministry of Health is the main focal point for coordinating, facilitating and regulating health research in Sri Lanka, since conduction of research is a non-devolved (reserved) subject to the provincial councils under the 13th amendment of the constitution.

- **Existing Framework of Health Research Facilitation in Ministry of Health**

The Management Services Circular No. 44 and 45 which was introduced in 2011 (as per budget proposal) has produced a tremendous impact on the conduction of research in Sri Lanka, including health research. (Copies of the relevant circulars and documents in relation to payment of research allowance are attached as Annexure I). A monthly research allowance at the rate of twenty five percent (25%) of the basic salary excluding allowances could be paid according to this circular to university lecturers and senior level officers engaged in research work in the public sector. A Research Sub Committee has been formulated in the Ministry of Health under the chairmanship of the Secretary of Health and three directors as members, in order to facilitate this research proposal approval and a research allowance payment process.

In addition to this existing system of payment of research allowance which is coordinated (in relation to health sector senior level officers) by the unit of the DDG -ET&R, there are two main institutions of health research facilitation under the Ministry of Health i.e. National Health Research Council and Medical Research Institute.

National Health Research Council

The DDG-ET&R unit is responsible for functioning in collaboration with the National Health Research Council (NHRC) to promote health research in Sri Lanka. There are representatives of six medical faculties of Sri Lanka, Sri Lanka Medical Association, Post Graduate Institute of Medicine and officials from Ministry of Health (Director General of Health Services, Deputy Director General – Education, Training and Research and 3 other Deputy Director Generals). Altogether there are 15 members.

Role of the National Health Research Council

1. **Formulation of National Health Research Council Act**

   Currently the process of finalizing the Act for the establishment of th National Health Research Council is underway and NHRC will be able t function as the apex body of promoting health research. This will b established for the purpose of facilitating the investment in research an development of health related fields; and to make provision for qualitativ and quantitative health care, and its management.

2. **Awarding of NHRC Research Grants**

   The research proposals submitted for funding are scrutinized for suitabilit by the NHRC and grants are made available for the approved proposal through the consolidated fund of the Ministry of Health. A total of 1(proposals were approved for 2012 with an allocation of Rs. 997,734.20.

3. **Revision and Formulation of Health Research Priorities**

   Health research in Sri Lanka is being prioritized and a publication had been made as "Priorities in Health Research" as guidance for the researchers in 2006. It is expected to revise and update these on a continuous basis and the NHRC in the process of revising these research priorities at the moment.

4. **Preparation of a draft national policy on human genetic data and material**

   This Policy will form the basis of legal provisions, regulations and procedures pertaining to general bio-medical research, clinical research, therapeutic trials including gene therapy, pedigree studies, genetic screening, DNA based diagnosis, DNA and Cell-Line Banking/Repository and Education. It was noted that a meeting is scheduled to be held at the National Science Foundation for finalization of the draft.

5. **Development of a Research Policy**

   Furthermore NHRC works with other core national research bodies in preparing the Health Research Policies for the country.

6. **Capacity building in relation to health research**

   In order to promote a research culture among the medical professionals, "Writing a research proposal" workshops are being conducted.

7. **Conduction of Research Ethics Forums**

   NHRC is conducting forums on research ethics for medical personnel and the dissemination of research findings to the policy makers.

Medical Researeh Institute

Additionally, the Medical Research Institute conducts and facilitates research activities through the conduction of ethics and scientific reviews, conduction and funding of research.

1. **Conduction of Ethical and Scientific Reviews**

   MRI scientific and ethics review committee is one of the recognized committees in Sri Lanka. During the year 2011, the ethics and scientific review committee of MRI has evaluated 49 research projects.

2. **Conduction of research**

   The MRI conducts research in diversified areas in the fields of Virology, Bacteriology, Parasitology, Rabies, Nutrition, Biochemistry, Histo-Pathology, Haematology, Immunology, Entomology, Molecular Biology, Pharmacology, Mycology and Animal Studies. The MRI conducted about 50 research projects last year, which is in contrast and much higher to the average of 15 researches conducted in previous years.

3. **Funding of research**

   The MRI also contributes to research activities through provision of funding and the total value of research grants provided through the MRI amounted to Rs. 28,852,114.00 during the year 2011 and for the year 2012, the total financial allocation for the research activities was Rs. 27 million.

- **Existing Ethical Review Processes of Health Research in Sri Lanka**

Ethical review is an essential and pioneering part of health research that ensures both the scientific validity of the research and also primarily the safety and rights of potential research participants or samples, which may include both humans and animals. This is especially important in health research since they involve data gathering in relation to sensitive and critical areas of humans and they may be subjected to discrimination and manipulation through the conduct of research. Additionally, ethical review is an essential pre-requisite for the presentation and publication of research in national and international forums and recognized medical journals. Therefore, Ethical Review Committees play an integral part in health research promotion and facilitation and additionally they enhance the regulation of research conduction and research publication.

According to the literature, an initial national ethical review committee was established in 1991 at the Natural Resources Energy and Science Authority (NARESA) and drew up draft codes for scientific research, animal experimentation, biomedical research on humans, and social sciences research. Later the Sri Lanka Medical Association (1992), the Sri Lanka Association for the Advancement of Science – SLAAS (1996) and the National Health Research Council (2000) under the Ministry of Health, were established. The National Bioethics Committee (NBC) of the National Science Foundation of Sri Lanka, set up in 2002, is the apex committee that fulfils the role of a National Ethics Committee for scientific research at the present time.

In 1981, the Faculty of Medicine, University of Colombo, became the first institution in Sri Lanka to establish an institutional Ethical Review Committee (ERC). But there is evidence to show that, the Faculty of Medicine at the Colombo Medical School was probably the first institution to start formal ethical review in Sri Lanka in the 1970s, and they review about 35 – 40 submissions annually using international guidelines. The University of Peradeniya started their ethics committee in 1984. The number of institutional ethical review committees (ERC) in Sri Lanka has increased rapidly over the past several years and in 2005 the Forum of Ethical Review Committees of Sri Lanka (FERCSL) was established.

FERCSL has formulated guidelines for Ethics Review Committees, a Model Application Form for Ethics Review, a Model Information Sheet and Consent Form, an Ethics Review Evaluation and Guidelines for Ethics Review of Research Proposals Involving Animals in Sri Lanka. These documents and guidelines can be downloaded from . The recognized members in this forum are listed in Annexure II.

All these Ethical Committees have common as well as their own unique and specific processes in approving research proposals. The Education, Training and Research Unit of Ministry of Health has recognized the ethical clearances of Ethical Review Committees of the Sri Lanka Medical Association and Universities for exemption of the review process, during the submission of research proposals for research allowance under the Management Services Circular No. 45. The process of submitting and approving the research proposals under this circular is illustrated as Annexure III.

Justification

The National policy document and framework of Sri Lanka, "Mahinda Chinthana – Vision for the Future - 2010" has recognized **improving facilities for medical research** as one of the main future strategies under the chapter 6.2 in relation to health which is termed as "Healthy Nation, Healthy People in a Healthy Community". It states that "Sri Lanka is in a better position to become a key centre in Asia for the provision of services relating to medical research and clinical trials which is an integral part of the Pharmaceutical Industry. The Government is now in the process of improving the necessary regulatory framework. This will help Sri Lanka attract more foreign research firms and provide long-term benefits to the country while enabling Sri Lankan health professionals to become global service providers." The same document stated that **the introduction of legislation to promote medical research by 2013** is one of the short term strategies for health development in Sri Lanka.

This policy document aims to convert education from a system that focuses largely on teaching to a system that focuses on teaching, research, development and social service. It states that the success of transforming Sri Lanka to a Knowledge Hub will greatly depend on the availability of an enabling environment and infrastructure to attract prominent international research and education institutions. Therefore, universities and research institutions will be encouraged to increase the quality and quantity of research undertaken, promote innovation, increase the acquisition and diffusion of technology and expand the economic and commercial potential of intellectual capital.

In the section of "Path to a knowledge based economy", it aims to adopt a National Human Resource Development (NHRD) policy to strategize research and development and to target postgraduate research in high-tech areas such as nanotechnology, biotechnology mechatronics, material science, microelectronics, Information Technology, satellite, clinical research, and telecommunications.

This policy document expects to establish National Centres of Excellence in several thrust areas in partnership with state research institutes, universities and the private sector under the Strategic Direction for Science, Technology and Innovation Strategy. In relation to health, the Medical Research Institute is expected to benefit under this strategy.

Therefore this policy framework has identified the value of research in diverse fields such as Education, Economy, Science and Technology, in addition to the Health,

and health related research has gained due recognition and importance within this national policy framework. These policy statements illustrate the value of promoting and regulating health research in Sri Lanka.

The most important aspect and ultimate applicability of conducting health related research in Sri Lanka is the provision of quality health care to the people. Evidence based health care, decision making and management is of immense importance in this context and locally relevant and applicable health research plays a vital role in producing these outcomes. But Sumathipala, A., et.al. after reviewing literature from five major journals in a calendar year has shown that, only 6.5% research is reported from 90% of disease burdened countries. Therefore it is quite clear that the 'evidence based medicine' we practice does come only from 10% of developed countries and their applicability locally is questionable at times. Nevertheless, high quality research conducted in developing countries can provide evidence of relevance and value even to the developed world.

Additionally, with the introduction of a research allowance for the Medical Officers under the Management Services Circular No. 45, the conduct of research within health care institutions under the Ministry of Health has increased tremendously and there is an increasing demand for ethical reviews in recent years with this rising trend of conducting research following the payment of research allowances. It was evidenced that, with the introduction of this payment of a research allowance, the quantity of research has increased while diminishing in quality and ethical considerations. This necessitates the requirement for better coordination and regulation of health research in order to enhance the quality of conducted research, through the introduction of best practices and guidelines for ethical review processes of ethical review committees of health care institutions in Sri Lanka.

Ethical review can be defined as a method, procedure, or perspective for deciding how to act and for analysing complex problems and issues through the use of research methodologies. Many different disciplines, institutions, and professions have norms for behaviour that suit their particular aims and goals in research conduction. These norms also help members of the discipline to coordinate their actions or activities and to establish the public's trust of the discipline. Ethical norms also serve the aims or goals of research and apply to people who conduct scientific research or other scholarly or creative activities. There is even a specialized discipline, research ethics, which studies these norms.

A study done by Sumathipala, A., et. al. revealed that ethical review in Sri Lanka is still an evolving process. It has shown that, out of the 291 theses from 1985 to 2005

available at the Postgraduate Institute of Medicine (PGIM) library only 34% had documented ERC approvals and 61% documented obtaining consent. Out of 79 full text original researches in International publications available electronically and originating from Sri Lanka between 1999 to 2004, only 38% had documented ERC approval and 39% documented obtaining consent. In the Ceylon Medical Journal 36% documented ERC approval and 37% documented obtaining consent. However, there was a positive trend in documenting these ethical requirements in local postgraduate research and in the local medical journal. Now it will be impossible to conduct research in Sri Lanka without ethical approval. However there is more to achieve in the quality of ethical review.

An evaluation done in 2005 by Perera J. et.al, illustrated that, sixty percent of Ethical Review Committees had only academic staff or doctors as committee members. It also shows that, the recruitment of members to the committee did not follow a formal process and no institutional guidelines were available for Ethical Review Committee members. It suggested that, in the current context there is a need to establish a National Framework for Ethical Review in Sri Lanka for educating researchers and to regularize the ethical review of research.

The Education, Training and Research Unit of Ministry of Health has recognized this current need and demand for ethical reviews and also identified numerous shortcomings in the existing practices of ethical clearance processes of Institutional Ethical Review Committees of health care institutions under the Ministry of Health. In this context, these guidelines are intended to supplement and strengthen the existing practices of Institutional Ethical Review Committees of health care institutions under the Ministry of Health.

The National Guidelines for the Establishment and Functioning of Ethical Review Committees in Health Care Institutions in Sri Lanka are expected to adapt and modify the current ethical review processes of health care institutions in Sri Lanka to suit the requirements of the Ministry of Health, in the context of a rising trend in health research. It is also expected to augment the ethical review guidelines produced by the Forum of Ethical Review Committees of Sri Lanka (FERCSL). Therefore, these guidelines are intended only to give a brief insight and guidance to the Institutional Ethical Review Committees of health care institutions under the Ministry of Health.

Objectives

General Objective

To enhance the evidence-based practices through conduction of ethically sound, relevant, applicable, scientific and quality research in health care institutions in Sri Lanka, conforming to national and international standards, while safeguarding the interests of research participants

Specific Objectives

1. To safeguard human beings, animals and the environment during the conduction of health sector research in Sri Lanka
2. To ensure the technical and methodological quality, integrity and coherence of health research conducted
3. To facilitate the research conduction process and to promote a research culture in health care institutions of Sri Lanka
4. To monitor and evaluate the ethical review processes of Institutional Ethical Review Committees of health care institutions under the Ministry of Health
5. To establish a transparent, accountable and uniform ethical review process, system and methodology within the health system of Sri Lanka which is compatible with international standards
6. To enhance the utilization of research findings in order to promote evidence-based practices in the health system of Sri Lanka

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6. The ultimate focus of the institutional ERC should be to promote and to ensure the contribution of research to the development of medical sciences and the health care delivery system of Sri Lanka, through enhancing evidence-based practices.

According to the Guidelines of the Forum of Ethical Review Committees of Sri Lanka, "The purpose of the ERC is to safeguard the dignity, rights, safety and well-being of all actual or potential research participants and ensure that animals, if used for research, are treated compassionately and humanely. The ERC should ensure the full review and evaluation of all ethical aspects of the research proposals it receives, before they are carried out, to make sure they follow ethical guidelines. The tasks of the ERC should be executed free of bias and influence." A detailed description of the role of an ERC can be obtained from these guidelines which can be downloaded from http://www.fercsl.net/FERCSL-Uniform%20 Guidelines.pdf

Composition of an Institutional Ethical Review Committee

It is the view of the Education, Training and Research Unit of Ministry of Health, as the focal point of the health research regulation in Sri Lanka, that the composition of the Institution ERC should be strictly adhered to, in order to ensure comprehensive scientific evaluation and ethical assessment of the submitted research proposals. Although there is a detailed description of the composition illustrated in the Guidelines of the Forum of Ethical Review Committees of Sri Lanka, it is the view of the Ministry of Health to modify it as follows in order to accommodate regional variations and the difficulty of finding required individuals at the regional level.

An Institutional ERC can be established in any health care institutions at or above the District General Hospital level. The ERC of this institution must also review research applications from other health care institutions below the level of District General Hospitals and Medical Officer of Health offices in the catchment area, since these institutions do not have the capacity and capability to establish an institutional ERC.

- There should be a minimum of 8 (7 Members with voting rights) members in the Institutional ERC and the suggested composition with minimum requirements will be as follows: (The first two members of this composition list are relevant only for ERCs' of provincial level health care institutions)

1. A Representative of the Provincial Director of Health Services of the province where the health care institution is located – who will act as the Chairperson. He / She should be a suitably qualified and preferably trained person on the Ethical Review Process.

2. A Representative of the Regional Director of Health Services of the district where the health care institution is located. He / She should be a suitably qualified and preferably trained person on the Ethical Review Process.

3. A Representative of the Head of the Institution who will be a suitably qualified person (preferably Medical Officer – Public Health) and a member but will not have voting or decision making power on submitted research proposals. He/she can give comments to the ERC on submitted proposals. He / She will also act as the chairperson in the ERCs' of the line ministry health care institutions.

   These health care service providers will assess administrative limitations, appropriateness and regional relevance of the submitted proposals.

4. Consultant Community Physician / Consultant Medical Administrator attached to the district / province where the health care institution is located (a person with a M.D. qualification in Community Medicine / Medical Administration should be appointed.)

5. Two (for provincial institutions) or Four (for line ministry institutions) Specialist Medical Officers

   This is the minimum requirement and depending on the availability of medical specialists, the head of institution can appoint any even number of members.

   These persons will give guidance to assess the scientific, technical and methodological validity of the submitted research.

6. An independent member who has expertise in legal matters and/or ethics (Attorney at Law); and

7. An independent member representing the community from the catchment area whose primary role is to share their insights about the communities from which the study participants are likely to be drawn. This person should preferably be a scientific expert who has an expertise in behavioural or social sciences.

- All these members are appointed for a period of two years.
- The Secretary to the ERC should be appointed from the available members at the initial meeting for a period of two years.
- Secretary of the ERC will act as the facilitator and should maintain records in relation to the minutes and decisions of the committee. He/she must convey the decisions to researchers after the authorization and concurrence of the head of the institution. He / she should also ensure that a final report of the research project is submitted to the ERC at the end of the research.
- If a proposal of any committee member is evaluated, such person/s should not be part of the ethics review process as there will be a conflict of interest.
- Every member of the Institutional ERC should declare their conflicts of interests at the beginning of every ERC meeting.
- The Quorum should be 4 individuals and at least one non-medical person should be present at the decision making stage.

The World Health Organization gives more guidance on the composition and can be downloaded from http://whqlibdoc.who.int/publications/2011/9789241502948_eng.pdf.

Role and Responsibility of the Head of the Institution

- Appointment of the members to the institutional ERC should be done at the sole discretion of the Head of the Institution. But he / she should ensure minimum conflicts and conflicts of interests among them.
- The Head of the Institution should not be a member of the Institutional ERC, but he/she should act as the person who authorizes and gives concurrence to conduct the research within the institution. The recommendation of the Head of the Institution is a must for submitting research proposals to the ERC.
- The Head of the institution where an ERC is established must ensure that the recommendations of all research conducting institutions are obtained through the relevant heads of institutions.
- The Head of the Institution should also undertake the administrative monitoring of the conduction of the research and should recommend the research to the Research Sub-Committee of the Ministry of Health.

- The composition of the institutional Ethical Review Committee should be approved by the Research Sub-Committee of Ministry of Health. For this purpose the Head of the Institution must forward a recommendation letter indicating the composition and names of the members of the ERC through the Deputy Director General (Education, Training and Research) and through the Director General of Health Services.

- The Head of the institution must get the approval through this same process, whenever there is a change in the composition in the members of the ERC.

- The Head of the Institution must continuously monitor the progress of conduction of approved research proposal for their conformity to the standards approved by the ERC.

- Head of the institution must ensure that all research conducted under his administrative purview (if Provincial Director of Health Services – he / she should ensure this for the research conducted within the province) has the ethical clearance from any approved and recognized Ethical Clearance Committee by the Ministry of Health.

- Head of the institution must send a detailed monthly summary of research proposals approved by the respective Ethical Clearance Committee of his / her institution or any other research conducted under his / her administrative purview (approved by another recognized Ethical Review Committee) to the office of the Deputy Director General (Education, Training and Research). The draft of such a monthly summary is illustrated in Annexure IV.

Role of Ministry of Health (Education, Training and Research Unit)

- The Education, Training and Research unit will ensure that the approval of the Ethical Review Committees by Research Committee is done promptly, once the composition of the committee is notified to the Ministry of Health. It is the responsibility of the unit to get this approval once the composition is received.

- The Education, Training and Research unit of the Ministry of Health will maintain a database (National Research Observatory) on approved research proposals by the institutional Ethics Review Committees.

- Regular training programmes will be established and conducted under the leadership of the Education, Training and Research unit of the Ministry of Health, with suitably qualified internal and external resources to update the knowledge and skills of institutional Ethics Review Committees.

Suggested Ethical Review Process for Institutional ERC

For the purpose of reviewing the submitted research proposals, the institutional ERC should utilize the following processes, methodologies and guidelines developed by the Education, Training and Research Unit of Ministry of Health.

- International Collaborative Research and Multi-Centre Studies (studies involving more than one centre which are located outside the relevant district) must not be evaluated solely by Institutional ERCs, but should also be subjected to a higher level of evaluation by the ERCs' recognized by the Education, Training and Research Unit of Ministry of Health (Sri Lanka Medical Association and Universities).
- Randomized Clinical Trials must be registered with the Sub-committee on Clinical Trial under the Cosmetics, Devices and Drug Regulatory Authority (CDDRA) of Sri Lanka and must not be evaluated by the institutional ERC. Details can be obtained from http://www.cdda.gov.lk
- Studies involving animals should not be evaluated by the institutional ERCs'.
- The Ethical Review Committee should display a public notice within the institution about the dates for which research proposals should be submitted to the ERC meeting of that particular month.
- All ERCs' should hold their meetings at least once a month, if the research proposals are available for or in line with the evaluation process.
- The ERC must provide guidelines to researchers and formulate appropriate formats for submission of research proposals and these suggested submission guidelines and forms are illustrated in Annexure V.
- The ERC must develop evaluation checklists for the evaluation of submitted research proposals or ERC can use formats which were developed by the Education, Training and Research Unit of Ministry of Health and these checklists are illustrated in Annexure VII and VIII.
- The ERC can adopt either of the following two mechanisms for evaluation i.e.
    - Each research proposal is evaluated by every member of the ERC
    - Each research proposal is evaluated by a technical and a methodological expert and a decision made by the ERC depend on their comments.

- The ERC can decide and select suitable external reviewers for the evaluation process, if the capacities of the existing members are inadequate. But this should be done with the prior approval of the Head of the Institution.

- The Ethical Review Committee should evaluate and give a decision on the research proposals submitted to them within a maximum period of two months from the date of submission.

- The ERC should give the following decisions on submitted research proposals i.e. "Recommended" or "Recommended with modifications" or "Not Recommended".

- If a research proposal is either "Not Recommended" or "Recommended with modifications", the ERC should give the reasons for rejections or modifications.

- The Secretary of the ERC must convey the decisions of ERC to researchers after the authorization and concurrence of the head of the institution. A sample format of Certificate of Ethical Clearance is illustrated in Annexure VI.

- He / she should also ensure that the final report of the research project is submitted to the ERC at the end of the research.

Detailed evaluation formats / check lists can also be downloaded from http://www.fercsl.net/FERCSL-Uniform Guidelines.pdf.

References

1. Dissanayake VHW, Lanerolle R, Mendis N., "Research ethics and ethical review committees in Sri Lanka: a 25 year journey". Ceylon Medical Journal 2006 51(3):110-113.

2. Fernando M, Dissanayake VHW, Corea E., "Ethics Review Committee Guidelines – A guide for developing standard operating procedures for committees that review biomedical research proposals". Forum of Ethics Review Committees, Sri Lanka, 2007. accessed

3. Forum for Ethical Review Committees in Asia and the Western Pacific, "12th FERCAP International Conference Development, Ethnicity, Culture and Ethical Health Research – Resource Material". 12th FERCAP International Conference, Colombo, Sri Lanka, 2012.

4. Perera J, Galaboda, DP, Gunawardena D., "Ethical review committees in Sri Lanka: a national framework is required". Ceylon Journal of Medical Science 2005 48(2): 62-66

5. Sumathipala, A. "Bioethics in Sri Lanka". Eastern Mediterranean Health Journal, 2006; 12: 73-9.

6. Sumathipala A, Siribaddana S, Hewege S, Lekamwattage M, Athukorale M, Siriwardene C Murray JA, Prince M. "Ethical approval and informed consent: analysis of biomedical publications originating from Sri Lanka". BMC Medical Ethics 2008, 9:3.

7. Sumathipala A, Siribaddana A, Patel V., "Under-representation of developing countries in the research literature: ethical issues arising from a survey of five leading medical journals". BMC Medical Ethics. 2004; 5:5

8. World Health Organization, "Standards and operational guidance for ethics review of health-related research with human participants". World Health Organization, Geneva, Switzerland, 2011. accessed

Annexure I

Circulars and Documents in relation to

Payment of Research Allowance as per Budget proposals – 2011

1. **Management Services Circular No. 44**
2. **Management Services Circular No. 45**
3. **Management Services Circular No. 45 (1)**
4. **General Circular No. 01-06/2012 (1) of Ministry of Health**
5. **Application form for the Submission of Research Proposals for Ministry of Health**

Management Services Circular No: 44

My No.DMS/A/8/21
Department of Management Services
General Treasury, Colombo 01.
10.03.2011.

All Secretaries to the Ministries,

Payment of Research Allowances as per the Budget Proposals 2011

In accordance with the budget proposals 2011, a monthly research allowance at the rate of twenty five percent (25%) of the basic salary excluding allowances could be paid to University Lecturers and Senior Level Officers engaged in research work in the public sector, subject to the following provisions. (This allowance does not entail any right to the pension or to any other statutory allowance).

02. **Officers Entitled to the Allowance**

I Lecturers and the senior level members of the academic staff of the universities who are in the permanent cadre.

II "Senior Level Officers" in accordance with the definition stipulated in the Public Administration Circular No. 06/2006 or officers in the Government Corporations and Statutory Boards who have completed at least 10 years of permanent service in "Academic and Research Services" or in a higher post according to the Management Services Circular No.30.

03. **Methodology**

(a) A proposal including the nature, time frame, and methodology of the research should be submitted to the Research Management Council/Committee mentioned in Para 04 and the approval of the said Council/ Committee for the research proposal should be obtained by the officers entitled to the research allowance as per Para 02.

(b) The research allowance can be obtained with effect from 01.01.2011 subsequent to the submission of the interim research report relevant to the said proposal to the Research Management Council/Committee within six (06) months and having obtained the approval thereof.

(c) Continuity of granting the research allowance at the end of two years will depend on the satisfaction of the Council /Committee with regard to publication of the final research report in an Internationally or Nationally Accepted Scientific Publication and/ or submission of the final research report to a relevant Symposium within the period of two years.

04. **Research Management**

(a) Research proposals of University Lecturers -

Research Committees accepted by the Senate of the relevant University.

(b) Research proposals of the officers serving in the field of agriculture in the Public Service, Government Corporations and Statutory Boards - Sri Lanka Council for Agricultural Research Policy (CARP).

(c) Research proposals submitted by the officers related to other fields - The Research Supervision Committee established under the Ministry of Technology and Research comprised of the following officers or the Sub Committees appointed by the said Committee as required.

- Mrs.Dhara Wijayatilake- Secretary to the Ministry of Technology and Research
- Doctor T.R.C. Ruberu- Secretary to the Ministry of Health
- Dr.R.H.S.Samaratunga- Secretary to the Ministry of Environment
- Mrs.Malini Pieris- Secretary to the Ministry of Plantation Industries
- Mr. Tilak Collure- Secretary to the Ministry of Industry and Commerce
- Dr.Saman Kelegama- Executive Director, Institute of Policy Studies
- Mr.B.Wijayaratne-Director, Sri Lanka Institute of Development Administration.

05. I. Research allowance shall not be paid in respect of research studies conducted prior to 28.02.2011.

II Research expenses should not be incurred from the provisions granted to the institutions from the Consolidated Fund.

III The research allowance should be incurred from the Expenditure Head No.1003 and in relation to Government Corporations and Statutory Boards, this research allowance should be borne from the relevant Expenditure Heads of salaries and other remunerations of each institution.

IV The research work expected by this Circular should not impede the duties of the permanent post.

06. This Circular is issued with the concurrence of the Ministry of Public Administration and Home Affairs, Ministry of Higher Education, Ministry of Agriculture and Ministry of Technology and Research.

Sgd. P.B.Jayasundera
Secretary to the Treasury and the
Ministry of Finance and Planning.

Copies to-

1. Secretary to the President
2. Secretary to the Prime Minister
3. Auditor General
4. Secretary to the National Salaries and Cadre Commission
5. Secretary to the Ministry of Public Administration and Home Affairs
6. Secretary to the Ministry of Higher Education
7. Secretary to the Ministry of Technology and Research
8. Secretary to the Ministry of Agriculture.

Management Services Circular No. 45

කළමනාකරණ සේවා චක්‍රලේඛ අංක :45

මගේ අංකය [illegible]
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2011.04.0[illegible]

[illegible]

2011 [illegible]

[illegible] 44 හා 44(i) [illegible]

02. [illegible] 2011 [illegible] (25%) [illegible]

03. [illegible] :

I. [illegible]

II. [illegible] 6/2006 [illegible] 30 [illegible]

04. [illegible]

(අ) [illegible] 03 [illegible] (Research Proposal) 05 [illegible] 2011.01.01 [illegible] 2011.01.01 [illegible] 2011.02.28 [illegible] 2011.02.28 [illegible]

(ආ) [illegible] 2011.12.31 [illegible] 05 [illegible] (Symposium) [illegible]

05. [illegible]

(අ) [illegible]

(ආ) [illegible] (CARP)

(ඇ) [illegible]

- [illegible]
- [illegible]
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- [illegible]
- [illegible]
- [illegible]

06. [illegible]

I. [illegible]

II. [illegible] 1003 [illegible]

III. [illegible]

07. [illegible]

[illegible]

පිටපත්:
1. [illegible]
2. [illegible]
3. [illegible]
4. [illegible]
5. [illegible]
6. [illegible]
7. [illegible]
8. [illegible]

Management Services Circular No 45(I)

My No: DMS/Circulars/2012
Department of Management Services
General Treasury
Colombo 01
10.10.2012

To all Secretaries to Ministries

Payment of Research Allowance according to the Budget Proposal 2011

The paragraph 05(C) of the Management Services Circular No: 45 issued under the above caption is hereby cancelled and the following paragraph is substituted.

" 05 (C) Research Proposals submitted by the officers relevant to the other fields By the Research Supervision Committee established under the Ministry of Technology and Research comprising of the following officials or the sub-committees approved by that Committee.

- Mrs. Dhara Wijethillake – Secretary, Ministry of Technology and Research
- Dr. R.H.S. Samarathunga – Secretary, Ministry of Petroleum Industry
- Doctor T.R.C. Ruberu – Secretary, Ministry of Civil Aviation
- Mr. W.M. Bandusena – Secretary, Ministry of Public Management Reforms
- Dr. Saman Kalegama - Executive Director, Institute of Policy Studies
- Mr. B. Wijayarathne - Director, Sri Lanka Institute of Development Administratior

Sgd. P.B. Jayasundera
Secretary to the Treasury & the
Ministry of Finance and Planning

Copies:

1. Secretary to the President
2. Secretary to the Prime Minister
3. Auditor General
4. Secretary, National Salaries and Cadres Commission
5. Secretary, Ministry of Public Administration and Home Affairs
6. Secretary, Ministry of Higher Education
7. Secretary, Ministry of Technology and Research

} Necessary instructions may be given appropriatel to the universities and relevant institutions

8. Secretary, Ministry of Agriculture

General Circular No. 01-06/2012 (1) of Ministry of Health

General Circular No. 01-06/2012 (1)

Ministry of Health
"Suwasiripaya"
385, Deans Road
Colombo 10.

30.03.2012

To All
Provincial /Regional Directors of Health Services
Directors of Teaching Hospitals/Provincial General Hospitals
Medical Superintendents of District General Hospitals/Base Hospitals
Directors/Heads of NIHS and all specialized campaigns

Guidelines for Research Allowance Payments as per the Management Services Circular No. 44

In accordance with the budget proposals 2011 a monthly research allowance of 25% of the basic salary excluding allowances is to be paid to university lecturers and senior level officers in public sector. Following guidelines has been revised and proceeded for research allowance claims.

1.0 The research proposal should include
- 1.1 Title of the research
- 1.2 Introduction
  - 1.2.1 Background information
  - 1.2.2 Justification
  - 1.2.3 General objectives
  - 1.2.4 Specific objectives
- 1.3 Literature review
- 1.4 Methodology
  - 1.4.1 Study design
  - 1.4.2 Study setting
  - 1.4.3 Criteria for eligibility
  - 1.4.4 Sampling method
  - 1.4.5 Sampling size
  - 1.4.6 Exclusion and inclusion criteria
  - 1.4.7 Study instrument
  - 1.4.8 Method of data collection
  - 1.4.9 Interviewers selection and training
  - 1.4.10 Data Analysis
  - 1.4.11 Ethical clearance
- 1.5 References-adhere to either Harvard or Vancure methods
- 1.6 Time frame and budget estimate.
- 1.7 Research proposal should be not more than 2500 words. The final report should be within10000 to 15000 words.

1.8 Font should be Times New Romans, page numbering bottom centre, margins top and left 1.5'' and bottom and right 1''with double spacing.

2.0 The number of investigators per research should not exceed more than 05 and one investigator should be nominated by the principle investigator to correspond on behalf of the research team, if needed.

3.0 Research proposal should be handed over to the relevant Technical Review Sub Committee (TRSC) in 03 hard copies and one soft copy with an application by research investigator and a copy of ethical review committee approval. If such committee is not available DDG (ET&R) will forward to relevant expert committee.

4.0 On approval by the TRSC the principal investigator should provide a hard copy and a soft copy of the research proposal to DDG (ET&R), the chairperson of the Research Management Subcommittee (RMSC).

5.0 On approval of the pre-proposal by the Secretary of Health the research investigator is entitled for a research allowance of 25% of the basic salary.

6.0 The continuation of the research allowance will require interim progress report in 6 months and that interim progress report should be produced to relevant Technical Review Sub Committee for recommendations for continuation of research allowance.

7.0 Continuity of granting the research allowance at the end of two years will depend on the satisfaction of the council/committee with regard to publication of final report in an internationally or Nationally accepted scientific publication or submission of the final report to a relevant Symposium within the period of two years.

Dr. Ravindra Ruberu
Secretary Health

ETR/E/F-03

Research allowance for Permanent/Senior Level Officers in Ministry of Health

Application Form

1.0 Details of the Research Proposal	
1.1 Research Title	
1.2 Name of the principal investigator	
2.0 Details of the Principal Investigator / Co-researchers	
2.1 Name with initial	
2.2 Full Name	
2.3 Date of birth	Date: Month: Year:
2.4 Age	
2.5 Gender (male/ female)	
2.6 Mariral Status	
2.7 NIC Number	
2.8 SLMC Reg. No	
2.9 Contact Details	2.9.1 Permanent Residential Address 2.9.2.Mobile 2.9.3 Residential 2.9.4 Office 2.9.5 Email
2.10 Current Working Station	
2.11 Date to Current Institution	
2.12 Salary Paying Institution	
2.13 Current Post	
2.14 Current Grace	

3.0 Declaration of researcher

I declare that,

1. The above facts are true and correct.
2. This is not full or pan of official duty.
3. This is not a copy of an alerted version of a previous research by me or another person.
4. Research expenses are not be incurred from the provisions granted to the institutions from the Consolidated Fund.
5. I have not obtained research allowance under the Management Services Circular No. 45 before as a Principal Investigator or as a co-researcher

- Please inform the name of the research title and the file number if you have already obtained research allowance under the Management Services Circular No. 45.

Research Title .....

.....

.....

File No. ETR/E/MC/RP/...../20.....

I am aware that if any fault in facts of my declaration I am subject to departmental disciplinary action.

Signature

Date

4.0 Observation and Recommendation of the Head of Institution / Decentralized Unit / Specialised Campaign.

I certify the particulars furnished by the medical officer, are correct. (State any incorrect informatieu, if furnished by the applicant)

Signature of Head of Institution

Signarure of Head of Decentralized Unit/ Special Campaign

Date

Date

Observation and Recommendation of the Regional Director of Health Services.

Signature

Date

5.0 Details of Co-researchers

Name of Co-researchers	NIC Number	Current Working Station	Date to current institution	Contact No.

6.0 Check List

Items	Submitted
Introduction and justification	
Objectives	
Literature review	
Methodology	
Time line / Gantt Chart	

7.0 Type of Research (mark the relevant cage only)

Type of Research	✓
Basic research	
Clinical trials	
Epidemiological research	
Evaluation research	
Qualitative research	
Quantitative research	
Service or programme monitoring and evaluation	
Other	

8.0 Declaration of Researcher

I declare that the above facts are true and correct.

Signature _____ Date _____

Please submit under mentioned documents to the ET & R Unit.

1. *Principal Investigator*
   a. Properly filled application form
   b. Certified copy of the NIC
   c. Latest pay slip original or certified copy
   d. Certified copy of the SLMC Registration
   e. Ethical review committee approval
   f. Approval of the Board of Study if PGIM candidate
   g. 3 hard copies & one soft copy of the research proposal including Gantt chart and budget report
   h. Annexure II & III

2. *Co-researchers*
   a. Properly filled application form
   b. Certified copy of the NIC
   c. Latest pay slip original or certified copy
   d. Certified copy of the SLMC Registration

Under mentioned letters should be addressed to DDG (ET&R) by the Principal Investigator

3. Request letter for the research allowance (Please fill Annexure I)
4. Date of commencement of the research (Please fill Annexure II)
5. i. Date of completion of 6 months of the research (Please fill Annexure I)
   ii. A progress report of the research should be submitted if the research has started six months before the date of submission.
   iii. And a progress report of the research should be submitted following six months from the date of commencement.
6. i. Date of completion of one year of the research (Please fill Annexure I)
   ii. Final report should be submitted at the end of first year.
   iii. Please refer essential requirements from the Management Services Circular No. 45 for the continuation of the research allowance for the 2nd year.

Annexure II

Recognized Ethical Review Committees by Ministry of Health as at 30.09.2013

Professional Colleges and Associations

1. Sri Lanka Medical Association
2. Sri Lanka College of Paediatricians

Universities

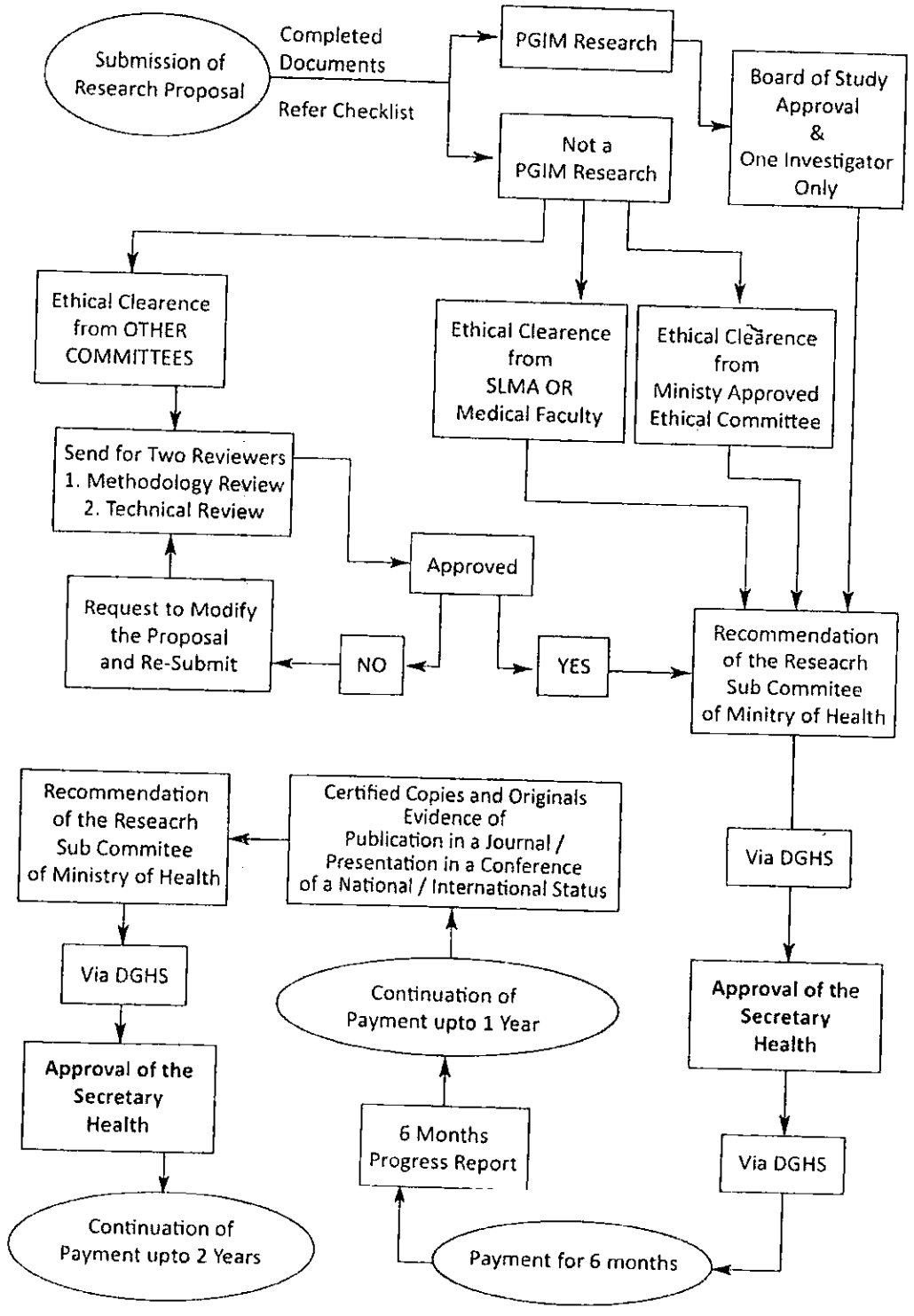
3. Faculty of Medicine, University of Colombo, Colombo
4. Faculty of Medicine, University of Peradeniya, Peradeniya
5. Faculty of Dental Sciences, University of Peradeniya, Peradeniya
6. Faculty of Medicine, University of Ruhuna, Galle
7. Faculty of Medicine, University of Kelaniya, Ragama
8. Faculty of Medical Sciences, University of Sri Jayewardenepura, Nugegoda
9. Faculty of Medicine, University of Jaffna, Jaffna
10. Faculty of Health Care Sciences, Eastern University, Batticaloa
11. Faculty of Medical and Allied Health Sciences, Rajarata University, Anuradhapura
12. Post Graduate Institute of Medicine – University of Colombo

Hospitals

13. National Institute of Mental Health, Mulleriyawa
14. Lady Ridgeway Hospital for Children, Colombo
15. Castle Street Hospital for Women, Colombo
16. National Eye Hospital, Colombo
17. National Institute of Health Sciences, Kalutara
18. Teaching Hospital, Kandy
19. Provincial General Hospital, Kurunegala
20. District General Hospital, Trincomalee

Annexure III

Process of Payment of Research Allowance



DOCUMENT CHECKLIST FOR SUBMISSION OF RESEARCH PROPOSALS FOR PAYEMENT OF RESEARCH ALLOWANCE UNDER MANAGEMENT SERVICES CIRCULAR NO 45

1. Request Letter addressed to DDG- ET&R
   (Request for Resaerch Allowance)
2. Application form of Principal Investigator
   (Signed by Head of the Institution)
3. Application forms of the Co- Investigators
   (signed by the Head of the Institution)

1, 2 and 3 Can be downloaded from www.health.gov.lk

4. All application forms (Principal and Co-investigators) should have certified copies of following documents
   1. National Identity Card
   2. SLMC Registration
   3. Salary slip of the previous month of each investigator
5. One soft copy and 3 hard copies of pre proposal / Research Proposal
   One Hard copy is enough If PGIM Post Graduate Proposal / Has a SLMA or University Ethical Clearence
6. Ethical clearance (from SLMA / Medical Faculty / Ministry of Health Approved Ethical Committee)
   - Certified Copy is needed
7. If the research is already started,
   Letter indicating the date of commencement
8. The progress/ interim report - in 6 months
9. If PGIM Candidate - Approval of the Board of Study
   - Certified Copy is needed

Annexure IV

Suggested Monthly Summary of Approved Research Proposals

Monthly Summary of Approved Research Proposals	
Name of the Institution	
Month / Year	
Number of Proposals Submitted	
Number of Proposals Approved	
Details of Approved Proposals	
Research Proposal 1	
1. Ethical Review Number	
2. Name of the Principal Investigator	
3. Topic of the Study	
4. General Objective	
5. Specific Objectives	
6. Type of Study (Descriptive Cross sectional / Case Control etc.)	
7. Is it a Multi Centre Study / Clinical Trial	
8. If so, relevant approvals obtained	
9. If Multi Centre Study – Other settings	
10. Budget (proposed)	
11. Funding Agency / Source of Funding	
12. Date of commencement	
Same information should be provided for the each submitted research proposal	
Signature of the Head of the Institution	

Should be sent by e-mail (ddgetr@health.gov.lk) or mail to the Deputy Director General (Education, Training and Research) at the end of every month
(A nil return should also be sent if there are no submitted proposals)

Annexure V

Format of the Application Form for submitting Research Proposals for the Ethical Review

This form should be completed and signed by the principal investigator.

1. Title of the Research Project
2. Details of the Principal Investigator (Please attach a copy of the Curriculum Vitae)
a. Name:
b. Qualifications:
c. Designation:
d. Name of the Institution:
e. Contact Details
i. Address of Correspondence:
ii. Residential Telephone No.:
iii. Office Telephone No.:
iv. Mobile No.:
v. E-mail:
3. Details of Co-Investigators

	Name	Qualification	Designation
1			
2			
3			

4. Details of the Research Project (Please indicate Y/N with a tick)	
a. Research project proposal (should be attached with 7 copies and soft copy to be submitted in a CD) including budget and funding source	
b. Recommendation letter from the Head of the Institution to the Ethics Review Committee	
c. Proposed date of commencement of the research	
d. Has it been submitted to any other Ethical Review Committees?	
e. If yes, what was the decision	
f. Is study a Randomized Controlled Trial	
g. Is study a Multi Centre Study	
h. Is study a Collaborative Research Study	
i. Is study use animals as research subjects	
j. What is the study instrument? (attach 7 copies of study instrument with Sinhala and Tamil translations and soft copy in a CD)	
k. What is the method of obtaining Consent (attach 7 copies of study instrument with Sinhala and Tamil translations and soft copy in a CD)	
l. How the information on research be conveyed to the study participants (attach 7 copies of information sheet with Sinhala and Tamil translations and soft copy in a CD)	
5. Any other relevant information	
I hereby certify that above particulars furnished by me are true and correct.	
Date:	Signature of the Principal Investigator:

For Office Use Only

Serial Number					
Check List					
Recommendation of the Head of Institution		Curriculum Vitae of the Principal Investigator			
Signed Declaration by the Applicant		Study Instrument (7 copies)			
Research Proposal (7 copies)		Consent form (7 Copies)			
All soft copies in a CD		Information sheet (7 Copies)			
Signature of the Receiver					

Annexure VI

Sample of a Format for a Certificate of Ethical Clearance (Adopted from the Ethical Review Committee – PGH Kurunegala)

දුරකථන අංක
தொலைபேசி இல
Telephone No. 037-2222261-63
037-2233906-09
037-2223873

දිනය
திகதி 2013-09-20
Date

මහනුවර රෝහල - කුරුණෑගල

போதனா வைத்தியசாலை - குருநாகல்

TEACHING HOSPITAL-KURUNEGALA

CERTIFICATE OF ETHICAL CLEARANCE

Principal Investigator:	Application Number :
	Approval Date :
	Approval Expiry Date :
Project title:	
Condition of Approval :	

This Certificate of Approval is valid for the above term provided there is no change in the protocol.

ADVERSE EFFECTS OR UNFORESEEN EVENTS: You should notify Institutional Ethical Review Committee of Teaching Hospital Kurunegala (IERC, TH Kurunegala) immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
Suspend or modify the project if the risks to participants are found to be disproportionate to the benefits.
Stop any involvement of any participant if continuation of the research may be harmful to that person.

COMPLAINTS: The researchers are required to inform IERC, TH Kurunegala promptly of any complaints made or expressions of concern are raised, in relation to the project.

AMENDMENTS TO THE APPROVED PROJECT (including changes in personnel): Requires the submission of a Request for Amendment form to IERC, TH Kurunegala and must not begin without written approval from IERC, TH Kurunegala. Substantial variations may require a new application.

ANNUAL REPORTS: Continued approval of this project is dependent on the submission of an Annual Report.

EXTENSION OF APPROVAL: The researches are required to submit a request to extend the period of validity of approval one month prior to approval expiry date along with the Annual Report.

FINAL REPORT: A Final Report should be provided at the conclusion of the project. IERC, TH Kurunegala should be notified if the project is discontinued before the expected date of completion.

MONITORING: Projects may be subject to an audit or any other form of monitoring by IERC, TH Kurunegala at any time.

President,
IERC, TH Kurunegala

Secretary,
IERC, TH Kurunegala

Annexure VII

ETR/E/EPR/07/2011/Review Format – A

GUIDELINES FOR THE REVIEWERS TO ASSESS THE RESEARCH PROPOSALS

METHODOLOGY REVIEW

Research Reference Number			Office Use Only
	Y	N	
Has the research protocol been recommended by a competent body?			To be completed by Principal Investigator during submission with the Signature
Are there any Conflicts of Interests?			
Has the researcher followed any applicable legal regulations or other guidelines relevant to Sri Lanka?			
Has the researcher obtained permission from the relevant authorities and Institutions where research is conducted?			
If a Randomized Controlled Trial - Is it registered under the Sri Lanka Clinical Trials Registry?			
If an Externally Sponsored Research - Is there a local collaborator? If so, Contact details and whether written agreement available?			

Name of the Reviewer			
Should the study be referred to another technical expert, policy maker or statistical expert?			
If YES, please inform the Chairman of ERC as soon as possible, suggesting a suitable person.			

Part A - Scientific Validity				
		Y	N	Comments
I	Are the research objectives stated clearly?			
II	Are the research objectives clearly defined?			
III	Is the study design appropriate in relation to the objectives / research question?			

Part B - Study Design				
PLEASE GO TO THE RESPECTIVE STUDY DESIGN AND MARK (Part B1 - B8)				
Part B1 - Systematic Reviews and Meta-Analysis		Y	N	Comments
I	Will all relevant studies included?			
II	Will selected articles appraised and data extracted by two independent reviewers			

III	Is sufficient details provided about the primary studies?			
IV	Is quality of the primary studies assessed?			
V	Are the researchers assessing the appropriateness of combining results to calculate a summary measure?			
Part B2 - Cohort Studies		**Y**	**N**	**Comments**
I	Prospective / Retrospective?			
II	Cohort representative of a defined group / population?			
III	All important Confounding factors identified?			
IV	All important exposures/ treatment /confounding factors/outcomes measured accurately and objectively?			
V	Were there important losses due to follow-up?			
VI	Were participants follow up for a sufficient length of time?			
Part B3 - Case Control Studies		**Y**	**N**	**Comments**
I	Were the cases clearly defined?			
II	Were the cases representatives of a defined population?			
III	How the controls were selected and were they drawn from the same population?			
IV	Were study measures identical for cases and controls?			
V	Were the study measures objective or subjective and is recall bias likely?			
Part B4 - Cross Sectional Studies		**Y**	**N**	**Comments**
I	Was the study sample clearly defined?			
II	Was the representative sample achieved?			
III	Were all relevant exposures / potential confounding factors and outcomes measured accurately?			
IV	Were patients with wide range of disease assessed?			
Part B5 - Case Series / Study		**Y**	**N**	**Comments**
I	Were cases identified prospectively or retrospectively?			
II	Were the cases representatives of the sample?			
III	Were all relevant exposures / potential confounding factors and outcomes measured accurately?			

Part B6 - Assess accuracy of a Test		Y	N	Comments
I	Does the sample of patients represent the full spectrum of patients?			
II	Was there a comparison with an appropriate "Gold Standard"?			
III	Did all the patients receive both the test under evaluation and the same "gold standard" test?			
IV	Were the tests performed independently with blinding of assessors to the results of the "Gold Standard" test?			
V	Were the cut offs that were used to classify patients as having a positive test result clearly described?			
Part B7 - Economic Evaluation		**Y**	**N**	**Comments**
I	How well the various costs and consequences of individual treatments have been identified, defined and measured?			
Part B8 - Qualitative Research		**Y**	**N**	**Comments**
I	Is theoretical basis of the study is adequately addressed?			
II	Is Sampling Strategy / Participant selection is justifiable?			
III	Whether the method is appropriate to achieve the desired objectives (Focus Group Discussions / Interviews etc.)?			
Part C - Methodology				
		Y	**N**	**Comments**
I	Is the strategies to address the key potential sources of biases of the methodology (Systematic Bias) is adequate?			
II	Is the strategies to address the key potential sources of biases of the researcher in Qualitative Research is adequate?			
III	Is there a reliable data analysis plan?			
IV	Do the sample size and statistical techniques have adequate power to produce reliable and valid results using the smallest number of research participants?			
V	Are the references / literature review appropriate and adequate?			

Part D - Assessment of Risks/Benefits for the Research Subjects				
		Y	N	Comments
I	Have adequate provisions been made for safety monitoring and termination of the research project?			
Part E - Respect for the dignity of the research participants				
	Part E1 - Informed consent	Y	N	Comments
I	Is the process for obtaining informed consent appropriate?			
II	Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable?			
III	Do you approve the incentives offered?			
IV	Will fresh informed consent be obtained if the procedures are changed during the research?			
V	Is there an opportunity for the participant to ask questions regarding the research?			
	Part E2 - Confidentiality	Y	N	Comments
I	Will the researcher collect only the minimum information/samples required to fulfil the study objectives?			
II	Is the privacy of the research participant safeguarded?			
Part F - Fair participant selection				
		Y	N	Comments
I	Has the study population been determined, primarily, based on the scientific goals of the study (and not on convenience, ethnicity, age, gender, literacy, culture or economic status)?			
II	Is the selection of participants (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?			
III	Will any group be stigmatized during the selection of participants?			
IV	Does selection of subjects favour any group?			
Part G - Responsibilities of the researcher				
		Y	N	Comments
I	Are there any conflicts of interest, including payments and other rewards?			
II	Are there any other ethical / legal/ social/financial issues in the study?			

Part H - Vulnerable group				
		Y	N	Comments
I	Can the research be equally well carried out in another, less vulnerable, group?			
Part J - Externally sponsored research				
		Y	N	Comments
I	Is the justification for the research to be carried out in Sri Lanka and not in the sponsoring country adequate?			
II	Is the research relevant to Sri Lanka?			
III	Are relevant local laws/ regulations/guidelines of each country adhered to?			
IV	Is the research responsive to cultural/social differences?			
V	If the data/biological samples are to be transferred overseas, is there adequate provision to safeguard the interests of the subjects and protect intellectual property rights?			
VI	Is there provision for results of research to be conveyed to relevant authorities in Sri Lanka?			
VII	Are any conflicts of interest resolved?			
Part K - Community based research				
		Y	N	Comments
I	Is the impact and relevance of the research on the community in which it is to be carried out acceptable?			

Additional Comments: (Please use separate sheet if necessary)			
Recommendation / Approval	**Y**	**N**	**Comments**
The research Study is suitable in present format and Approved			
The areas mentioned below should be modified and the project is approved subjected to these minor modifications			
The areas mentioned below should be modified / rewritten according to the following instructions and the project resubmitted for evaluation			
The study is not suitable in the present format (Give reasons)			
Name of Reviewer:.....			
Signature:	Date:...../...../.....		

Annexure VII

ETR/E/EPR/07/2011/Review Format – B

GUIDELINES FOR THE REVIEWERS TO ASSESS THE RESEARCH PROPOSALS

TECHNICAL REVIEW

Research Reference Number			Office Use Only
	Y	N	
Has the research protocol been approved by a competent body?			To be completed by Principal Investigator during submission with the Signature
Are there any Conflicts of Interests?			
Has the researcher followed any applicable legal regulations or other guidelines relevant to Sri Lanka?			
Has the researcher obtained permission from the relevant authorities and Institutions where research is conducted?			
If a Randomized Controlled Trial - Is it registered under the Sri Lanka Clinical Trials Registry?			
If an Externally Sponsored Research - Is there a local collaborator? If so, Contact details and whether written agreement available?			

Name of the Reviewer			
Should the study be referred to another technical expert, policy maker or statistical expert?			
If YES, please inform the Chairman of ERC as soon as possible, suggesting a suitable person.			

PART A - Scientific Importance				
		Y	N	Comments
I	Will the study lead to improvements in human health and wellbeing or increase knowledge?			
II	Is selected subject appropriate and timely?			
III	Is the study's research question relevant? Important topic / Relevant to the field of work of the researcher			
IV	If the study is a replication of a previous study, is it justified?			
V	Does the study add anything new? Adds to the knowledge - improve the validity of previous research			

VI	Does the study add anything new? ability to generalize by extending the original research findings to a new group			
VII	Is there a utilization value of the results of the project?			
VIII	Can the intervention studied be practically implemented?			
IX	Is the management of logistics of the project appropriate?			
X	Are the references / literature Review appropriate and adequate?			
Part B - Assessment of Risks/Benefits for the Research Subjects				
		Y	N	Comments
I	How safe is the intervention used in the research?			
II	Is the justification of predictable risks and inconveniences weighted against the anticipated benefits for the research participant and the concerned communities adequately?			
III	Are there any plans to withdraw or withhold standard therapy for the purpose of research and such actions if any justified?			
IV	Is the standard of care the best available locally?			
V	Is the medical and psychological support for the participants adequate?			
VI	Is the site including support staff, facilities and emergency procedures adequate?			
VII	Have adequate provisions been made for safety monitoring and termination of the research project?			
Part C - Respect for the dignity of the research participants				
		Y	N	Comments
Part C1 - Informed consent				
I	Is the process for obtaining informed consent appropriate?			
II	Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable?			

III	Do you approve the incentives offered?			
IV	Will fresh informed consent be obtained if the procedures are changed during the research?			
V	Is there an opportunity for the participant to ask questions regarding the research?			
	Part C2 - Confidentiality	Y	N	Comments
VI	Will the researcher collect only the minimum information/samples required to fulfil the study objectives?			
VII	Is the privacy of the research participant safeguarded?			
	Part D - Fair participant selection			
		Y	N	Comments
I	Has the study population been determined, primarily, based on the scientific goals of the study (and not on convenience, ethnicity, age, gender, literacy, culture or economic status)?			
II	Is the selection of participants (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?			
III	Will any group be stigmatized during the selection of participants?			
IV	Does selection of subjects favour any group?			
	Part E - Responsibilities of the researcher			
		Y	N	Comments
I	Is the medical care to be provided to the research participants during and after the research adequate?			
II	Are there any conflicts of interest, including payments and other rewards?			
III	Are there any other ethical/legal/ social/financial issues in the study?			
	Part F - Vulnerable group			
		Y	N	Comments
I	Can the research be equally well carried out in another, less vulnerable, group?			

Part G - Externally sponsored research				
		Y	N	Comments
I	Is the justification for the research to be carried out in Sri Lanka and not in the sponsoring country adequate?			
II	Is the research relevant to Sri Lanka?			
III	Are relevant local laws/ regulations/guidelines of each country adhered to?			
IV	Is the research responsive to cultural/social differences?			
V	If the data/biological samples are to be transferred overseas, is there adequate provision to safeguard the interests of the subjects and protect intellectual property rights?			
VI	Is there provision for results of research to be conveyed to relevant authorities in Sri Lanka?			
VII	Are any conflicts of interest resolved?			
Part H - Community based research				
		Y	N	Comments
I	Is the impact and relevance of the research on the community in which it is to be carried out acceptable?			

Additional Comments: (Please use separate sheet if necessary)			
Recommendation / Approval	**Y**	**N**	**Comments**
The research Study is suitable in present format and Approved			
The areas mentioned below should be modified and the project is approved subjected to these minor modifications			
The areas mentioned below should be modified / rewritten according to the following instructions and the project resubmitted for evaluation			
The study is not suitable in the present format (Give reasons)			
Name of Reviewer:.....			
Signature:	**Date:**...../...../.....		