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சுகாதார மற்றும் சுதேச வைத்திய அமைச்சு
Ministry of Health & Indigenous Medicine

General Circular Number: 01-30/2020

All Provincial Secretaries of Health,
All Provincial/Regional Directors of Health Services,
All Heads of Line Ministry Institutions,
Chairman, National Medicines Regulatory Authority,
President, Sri Lanka medical Association,
Director, Sri Jayewardenepura General Hospital,
Director, Vijaya Kumaranathunga Memorial Hospital,

Conduct of Health and Health-related Research in Healthcare Institutions, other Institutions and Community Settings in Sri Lanka.

This circular will rescind the previous two circular letters issued on the 10/11/2017 under the file number ETR/E/NHRC-Mts/2017 and on the 29/04/2015 under the file number ETR/E/NHRC-Mts/09/2014 by the DGHS, Ministry of Health on "**Conduct of Health and Health-related Research in Healthcare Institutions, other Institutions and Community Settings in Sri Lanka".**

Research in health is considered as the cornerstone of knowledge generation and is essential as it contributes to the making of evidence-based decisions in health, health care and for improvement of quality of life and wellbeing of people and contributes to sustainable developement. Health research and health related research conducted in Sri Lanka are expected to adhere to highest scientific standards, ethical norms, legal requirements and to administrative guidelines.

In this context, the Researcher and the Head of the Institutions where the research work is being planned and is carried out must ensure that the research adhere to the guidelines given below.

1. **Clinical Trials**

i. Clearance from Ethics Review Committee (ERC) for clinical trials or an interventional study including field trials for medicine/s as specified under iii should be obtained from an ERC recognized by the National Medicines Regulatory Authority (NMRA). Ethics Review Committees recognized by the NMRA are:

- ERC, Sri Lanka Medical Association
- ERC, Faculty of Medicine, University of Colombo
- ERC, Faculty of Medicine, University of Peradeniya
- ERC, Faculty of Medicine, University of Ruhuna
- ERC, Faculty of Medicine University of Kelaniya

- ERC, Faculty of Medical Sciences, University of Sri Jayewardenepura
- ERC, Faculty of Medicine, University of Jaffna
- ERC, Medical Research Institute, Ministry of Health
- ERC, Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka

ii. Approval from National Medicines Regulatory Authority (NMRA), should be obtained and the certificate granting ethics clearance should be submitted to the Sub-Committee on Clinical Trials (SCOCT) when applying for approval for the clinical trial or an interventional study.

iii. NMRA approval is required for clinical trials involving **unregistered medicines** and **registered medicines** where the proposed clinical trial is outside the conditions of such registration and they may include changes to the, **indications and clinical use, target patient population, routes of administration and dosage regimens.** The Clinical Trial Evaluation Committee (CTEC) of the NMRA guides the Authority in its decision-making regarding types and clinical trials mentioned above. Relevant guidelines can be found on **www.nmra.gov.lk.**

iv. Clinical trials and other interventional studies should be registered preferably in the Sri Lanka Clinical Trials Registry (SLCTR) managed by the Sri Lanka Medical Association or in a WHO recognized Clinical Trials Registry.

v. Participants should be insured covering the costs of medical care arising out of the clinical trial or intervention, where such risk is anticipated.

The researcher should submit copies of the ERC certificate, approval certificate of the NMRA, certificate of registration by Clinical Trial Registry and the certificate of participants insurance coverage to the relevant head of the institution where the research is to be conducted, to obtain the approval from the institution and Regional Director of Health Services (RDHS) when the research is to be carried out in the community.

Copies of the ERC certificate, certificate of registration issued by the Clinical Trials Registry, approval certificate of the NMRA (where relevant), insurance coverage (where relevant) and the recommendation of the Head of the Institution should be submitted to the Education, Training and Research (ET&R) Unit of the Ministry of Health for information.

2. International Collaborations

When research involves foreign collaborations, transfer of biospecimens and protected health information, and/or funding from an international body, the researcher should submit following documents and information to the Education, Training and Research (ET&R) Unit to obtain the approval of the Ministry of Health.

i. The research protocol (including declaration of conflicts of interest, intellectual property rights, if any) both in soft and hard copy form, duly signed Memorandum of Understanding (MOU), and information about funding agency and amount

ii. A copy of the ERC certificate

iii. Observations and recommendation of the head of the institution where research is to be carried out and RDHS when the research is carried out in the community.

All researchers and research institutes should comply with relevant sections of Cirular PS/S /SB/Circular/06/2019 issued by the Presidential Secretariat.

3. Cohort studies and patient registries

Registration of cohort studies and patient registries for resaerches are required to submit to the Education Training and Resaerch Unit of the Ministry of Health information on the Title,Principal Investigator, Co -Investigators, Duration of the study, Progress reports, Area of study, Date of commencement, Date of Administrative clearance from ET&R unit, Date of Termination and the date of ERC approval.

4. Other research

For all other health and health related research, the researcher should submit the research protocol and a copy of the ERC certificate to obtain approval of the Head of the Institution in the case of hospital/clinic-based research and/or the Regional Director of Health Services, where the research is to be carried out in a community setting or a university or any other institution.

Where the Head of the Institution or the Regional Director of Health Services is unable to make a decision all related documents and observations, should be referred to the ET&R Unit of the Ministry of Health.

A summary of the final report of the research should be submitted to the ET&R Unit of the Ministry of Health and the National Health Research Council for updating the health research database.

You are hereby informed to follow the above guidelines and obtain the approval from relevant authority when and where health and health related research is conducted in Sri Lanka.

Dr. S. H. Munasinghe
Secretary
Ministry of Health & Indigenous Medical Services
"Suwasiripaya",
385, Rev. Baddegama Wimalawansa Thero Mawatha,
Colombo 10, Sri Lanka.

Secretary
Ministry of Health and Indigenous Medical Services

cc: Additional Secretary (Medical Services/ Public Health Services)
Director General of Health Services
All Deputy Director Generals
Chai person National Health Research Council

List of documents to be submitted for Administrative Clearance from the Ministry of Health

Component	Available (Mark √)
1. Proposal	
a/ Detailed proposal	
b/ Certificate of Ethical clearance	
c/ Information sheet / consent forms	
d/ Study instruments – Eg questionnaire	
2. Budget	
3. Source of Funding Details	
4. Collaboration agreement	
5. Material Transfer Agreement Details (If relevant)	
6. No objection certificate from institutional head	
7. If it is a clinical trial, it should be registered in the Sri Lanka clinical trial registry of SLMA	
8. Request letter addressing DDG/ ETR to grant permission (Include corresponding author's contact number and email)	