SRI LANKA CLINICAL TRIALS REGISTRY

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17th May 2019

Prof. Sureka Chackrewarthy
Chairperson
Ethics Review Committee
Faculty of Medicine
University of Kelaniya
PO Box 6, Thalagolla Road
Ragama

Dear Prof. Chackrewarthy,

Re: Ethics Review Committee approval of Clinical Trials and ensuring registration with the Sri Lanka Clinical Trials Registry

The Sri Lanka Clinical Trials Registry (SLCTR) is a primary registry of the WHO International Clinical Trials Registry Platform (ICTRP). The SLCTR is recognized by the Ministry of Health as the National Clinical Trials Registry and provides a platform for the prospective registration of interventional trials done in Sri Lanka and other countries.

For the purposes of registration, the WHO defines a clinical trial as "any research study that prospectively assigns **human participants** to one or more **health-related interventions** to evaluate the effects on **health outcomes**. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials".

The WHO International Standards for Clinical Trial Registries (updated in 2018) makes several recommendations to ensure transparency and accountability of clinical trials.

1. As Ethics Review Committees (ERCs) play an essential role in ensuring transparency and accountability of research, I wish to bring to your kind notice the following

    i. The Scientific Title of the trial contain all elements of Participants, Intervention, Comparator and Outcomes (PICO). These elements are also important components of research questions in interventional studies.

    ii. The type of study design E.g. "Randomised Controlled Trial"/ "Non Randomised Controlled Trial" should be included in the title.

    iii. ERC approval details and ERC contact details are now a mandatory part of the WHO Trial Registration Data Set. ERC approval letters (including extension letters) should include **date of approval, duration of approval** and **reference number**.

2. The National Medicines Regulatory Authority (NMRA) of the Ministry of Health, has stipulated that approval is needed for clinical trials conducted in Sri Lanka on new drugs/chemical entities or where the registered interventional product is planned to be used outside the approved indications.

3. We note that certain trials are carried out in 2 stages where stage 1 is an initial observational study and stage 2 is an interventional study (clinical trial). In such instances the SLCTR will request the ERC to confirm approval of the interventional component.

4. Prior Ethics Review Committee approval is essential for clinical trial registration with the SLCTR.

I would be grateful if you could take steps to guide researchers to ensure that the above recommendations are met.

Thank you.

Yours sincerely,

Prof Colvin Goonaratna
Chairperson
Sri Lanka Clinical Trials Registry