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தேசிய மருந்துகள் ஒழுங்குபடுத்தல் அதிகார சபை

National Medicines Regulatory Authority

National Medicines Regulatory Authority, No: 120, Norris Canal Road, Colombo 10.

To Chairpersons/Secretaries of all accredited Ethics Review Committees

ERC, Faculty of Medicine, University of Colombo
ERC, Faculty of Medical Sciences, University of Sri Jayewardenepura
ERC, Faculty of Medicine, University of Peradeniya
ERC, Faculty of Medicine, University of Kelaniya
ERC, Faculty of Medicine, University of Ruhuna
ERC, Faculty of Medicine, University of Jaffna
ERC, Faculty of Medical and Allied Sciences, University of Rajarata,
ERC, Medical Research Institute, Colombo
ERC, Sri Lanka Medical Association, Colombo

Dear Sir/Madam

Regulatory Control over Trials Involving New Interventions & Interventions Outside Approved Use


The National Medicines Regulatory Authority has charged its Sub-Committee of Clinical Trials to provide regulatory oversight to clinical trials carried out in the country and where suitable to endorse such trials to proceed. The criteria for requiring our approval are clinical trials involving unregistered interventions or where the intervention is outside the approved use. Guidelines for conducting such research is available on the NMRA website.

It has come to our notice that a number of such trials have been launched without having been submitted to this committee. This may be simple ignorance of behalf of the investigators. Nevertheless, I would be grateful if this requirement can be re-enforced through your application process and website to make this mandatory review better known.

The committee works to give approval where suitable in the shortest possible time and minimise the impact of the regulatory process on valuable clinical research.

We would appreciate your co-operation in this matter.

Yours faithfully


Dr. Kamal Jayasinghe,
Director General/Chief Executive Officer,
National Medicinal Regulatory Authority,

Dr. Kamal Jayasinghe
MBBS, DPM, MS-Med Admin, MBA, DipPhA
Chief Executive Officer
National Medicines Regulatory Authority
120, Norris Canal Road, Colombo 10

Copy: Secretary/Sri Lanka Clinical Trials Registry