

PRESS RELEASE OF THE NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE (NHSRC) ON THE HEALTH RESEARCH REVIEW AND CLEARANCE IN MALAWI

The NHSRC, as a national health research ethics committee of the Government of Malawi operating under strictest principles of morality, integrity, and professionalism in health research governance, and operating under its internationally acclaimed standard operating procedures and guidelines, reserves **NO** intention to engage with any stakeholder **through the Press** on any matter pertaining to its operations as doing so is flouting its established Standard Operating Procedures and Principles of Government Communication. Occasionally, the NHSRC is morally obligated to issue some Press Release on matters of bioethical legitimacy pertaining but not limited to the protection of human research participants and health research governance in Malawi. In this regard, the NHSRC would like to share with members of the general public some information pertaining to the health research review and clearance system in Malawi as follows;

(a) Structure of the Health Research Review and Clearance in Malawi

The following are the established structures which review and clear health research protocols in Malawi:

(i) *National Health Sciences Research Committee (NHSRC)*

It reviews and clears all types of health research proposals /protocols except those from the Faculty members of the College of Medicine (COM) and Kamuzu College of Nursing (KCN) and their collaborators. It also reviews and clears research studies that have been specifically defined to be in the category of ***national interest studies regardless of their origin because of their sensitive, political and safety implications at individual and national level.*** The Ministry of Health through the Research Unit is the Secretariat of NHSRC.

(ii) *College of Medicine Research and Ethics Committee (COMREC)*

It reviews and clears research proposals/protocols from Faculty members of COM and KCN, and their collaborators **except** those studies in the category of ***national interest studies which are referred to the NHSRC.*** COMREC is an institutional review board/institutional research ethics committee of the College of Medicine.

(iii) *Pharmacy, Medicines and Poisons Board (PMPB)*

Through its Clinical Trial Review Committee (CTRC), the PMPB reviews and certifies clinical trials involving the investigation of new pharmaceutical products not registered in Malawi. It also reviews clinical trials involving pharmaceutical products already registered in Malawi but where the trial uses such products in a new formulation and dosage other than the one the product is already registered in for purposes of the clinical trial.

(b) Specific Requirement on Payment of Fees

Like all committees of this type in the world, NHSRC, COMREC and CTRC of PMPB have specific requirements including fees. The fee structure is as follows:

- A non refundable amount of US\$150 for non-Malawian researchers and MK500 for Malawian researchers shall be paid upon submission of their research proposals. The NHSRC will not review any proposal if this fee is not paid at the time of submission of the proposal.
- If after review the proposal is approved, the investigator shall pay to the Ministry of Health a fee of 10% of the total budget indicated in the proposal for institutional capacity strengthening and operations of the NHSRC. COMREC charges in the same way but payable to College of Medicine. *(The CTRC fee, the US\$ 150 and K500 fees as indicated above are included in the 10%).*
- *Payment of the 10% fee shall be made for all research projects that have been approved by NHSRC prior to commencement of the research study.*

The NHSRC, however, notes that in some developed countries such committees charge as high as 45% of the total budget.

(c) Rationale for the Fee and Its Specific Use

World over, Governments do not have adequate resources to meet all the cost of the affairs of health research ethics review committees and health research governance. Low income countries like Malawi are even more disadvantaged and vulnerable. Money realized from fees is used to complement Government resources for undertaking the following key activities in line with the NHSRC standard operating procedures, guidelines and functions;

- for holding technical meetings at which research proposals/protocols are reviewed by expert members;
- for carrying out inspection, monitoring and evaluation of approved research studies;
- for tracking down of illegal studies
- for providing continuing education to members serving on these committees;
- for organizing national dissemination fora of results emanating from the approved research studies; and
- in some cases to offset administrative overhead costs where a research study/project is affiliated to a public health facility.

NB : Any researcher or research organisation not willing to comply with the Requirements, Procedures, Guidelines and Regulations of the Malawi Health Research Review Committees is not forced to conduct research in Malawi but is free to go to any country in the world where such research related requirements do not exist .

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