NATIONAL HEALTH RESEARCH AUTHORITY

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To All:
Heads of Health Research Ethics Committees/Research Institutional Review Boards
Health Researchers
Heads of Health Research Institutions
Heads of Health Establishments where health research is conducted
Heads of Academic Institutions where health research is conducted

C.C. All Members of the National Health Research Ethics Board

Dear All,

Subject: Review of Clinical Trials and Special Protocols by NHREB

As you may be aware, the Section 14, Subsection (3) of the Health Research Act No. 2 of 2013 states as follows:
"(3) The Board shall give ethical approval for—
(a) All clinical trials involving medicines, vaccines or other biological products, new therapeutic regimes, as well as invasive diagnostic procedures;
(b) Multi-center and multi-national collaborative health research;
(c) Health research which is fully or partially initiated, financed and wholly or partly carried out by External donors or international agencies;
(d) Health research which is carried out by an international agency or agencies with bilateral or multi-lateral collaboration or agreements with the Government; and
(e) Health research proposals that meet the health research ethics guidelines."

In summary the National Health Research Ethics Board (NHREB) is mandated to review and approve the above categories of research.

The current practice is that all these Protocols first go through an Ethics Committee and then referred to NHREB for final approval. Ethics Committees and Researchers have expressed concern over this 'double review' process as it takes time.

Hence the NHRA Council at its last sitting on April 8, 2020 resolved as follows:

a) The 'double review' process be done away with to reduce on the turnaround times for such Protocols; this means that all the special protocols and Clinical Trials

cited under section 14, subsection (3) of the Health Research Act should with immediate effect go through NHRA Secretariat to NHREB for review.

b) The review of the Special Protocols and Clinical Trials by NHREB should attract a non-refundable Review Fee of K4,000.00 per Protocol to cover the costs of NHREB monthly sittings.

All Researchers are informed accordingly. For research currently under your review, proceed to complete the review and advise the researcher to submit the same to NHREB; in this case the researcher will not be double charged.

Kindly note that the NHREB may at its sole discretion may delegate some of its functions to an accredited Research Ethics Committee as provided for under the Health Research Act No. 2 of 2013.

Thank you for your usual support and cooperation.

Prof. Godfrey Biemba
CEO/Director
NATIONAL HEALTH RESEARCH AUTHORITY