NATIONAL HEALTH RESEARCH AUTHORITY

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Date: 10th April, 2020

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. PS Technical Services, MOH
C.C. Council Chairperson and Vice-Chairperson
C.C. All Members of the National Health Research Ethics Board

Dear All,

Subject:
1.0 Ethical clearance of research protocols during COVID-19 Pandemic in Zambia,
2.0 Review of Clinical Trials and Special Protocols by NHREB
3.0 Registration and Accreditation of Researchers, Research Institutions, Academic Institutions conducting health research, health establishments at which health research is conducted
4.0 Designation of Bio-banks

This Circular letter is issued to communicate information on four (4) topics:

1.0 Ethical clearance of research protocols during COVID-19 Pandemic in Zambia As you are all aware, the global community has been ravaged by the COVID-19 pandemic, which has resulted into thousands of deaths and over 1 million morbidities.

As part of the response to this Pandemic, the World Health Organization (WHO) has developed a Research and Development Blue Print (Powering Research to Prevent Epidemics) called "A Coordinated Global Research Roadmap." To implement this Roadmap, WHO has proposed three Strategic Approaches:

a) A defined Global Research Roadmap with defined timelines and accountability;
b) National research plans at the core of research agenda;
c) Coordinated implementation of critical research (using core generic protocols when possible).

In line with this Global Research Strategy and in line with its statutory mandate of advising the Minister on all matters related to health research, as well as its mandate

of promoting and coordinating health related research for the country, the National Health Research Authority (NHRA) has developed a COVID-19 Research and Innovation Plan for Zambia. The main objectives of this plan are two-fold:

a) To facilitate a Zambian coordinated research response to COVID-19;
b) To mobilize resources for COVID-19 research in a coordinated manner.

This Plan is attached for your perusal and action. Of particular note for Research Ethics Committees and Research Institutional Review Boards (IRBs) is **section 4.3 on page 15.** Kindly do all you can to adhere to these turnaround targets.

2.0 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. Should a researcher submit such a Protocol to your Committee please advise them 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.

3.0 Registration and Accreditation of Researchers, Research Institutions, Academic Institutions conducting health research, health establishments at which health research is conducted

I wish to inform you that it is a statutory requirement that all researchers, research institutions, academic institutions where health research is conducted, health establishments where health research is conducted, and health research ethics committees must be registered and accredited by the National Health Research Authority as provided for under the Health Research Act and now operationalized by Statutory Instrument No. 25 of 2020. Further guidance on procedures to be followed will be provided in due course and the Statutory Instrument will be shared accordingly. The registration process will start as soon as guidelines have been shared. At that stage we shall advise on the deadline for registration and accreditation.

4.0 Designation of Bio-banks

I also wish to inform Statutory Instrument No. 24 of 2020 has now provided for research establishments to apply for a License to operate a Bio-bank. Further guidance on procedures to be followed will also be provided in due course and the Statutory Instrument will be shared accordingly.

Thank you for your usual support and cooperation.

Prof. Godfrey Biemba
CEO/Director
NATIONAL HEALTH RESEARCH AUTHORITY