NATIONAL HEALTH RESEARCH AUTHORITY

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Date: 13th January, 2021

To all Researchers and Research Institutions
C.C:
Chairperson, NHREB
Chairpersons of all Research Ethics Committees
Director General, ZAMRA

Dear Sir/Madam

Re: Guidance on conducting research during the COVID-19 and other Epidemics in Zambia

Reference is made to the above captioned subject.

As you are all aware, the COVID-19 pandemic has worsened in Zambia; with an increase in number of cases reported daily, an increase in the severity of disease resulting in more patients needing intensive care, and an increase in the number of deaths associated with or due to COVID-19.

In the light of the above, the National Health Research Authority (NHRA) in line with its mandate to regulate health research in Zambia as provided for in the Health Research Act No. 2 of 2013, and in consultation with the Zambia National Public Health Institute (ZNPHI) has decided to provide further guidance to researchers, research institutions, academic institutions conducting health research, and health establishments conducting research in Zambia.

The guidance is meant to protect both the researchers and the research participants against contracting COVID-19 during a research undertaking. It is also meant to ensure that research responds better and contributes more to the emergency response. All those involved in health research in Zambia should adhere to the attached guidelines. Thank you and stay safe.

Yours sincerely,

Prof. Godfrey Biemba
Director/CEO
National Health Research Authority

The National Health Research Authority Ten Point Guidance on conducting research during the COVID-19 and other Epidemics in Zambia

1. *Undertaking of any research activity must not compromise the health and safety of individuals involved or communities in which they are being conducted*

All requests for authority to conduct research in Zambia submitted to the National Health Research Authority (NHRA) must be accompanied by a document signed by the Principal Investigator detailing all measures put in place to protect both the research team and the research participants against COVID-19 as per current Zambian and international guidelines. All researchers, who will have contact with research participants must have negative COVID-19 test results before field work.

The Principal Investigator must ensure that Research Field Staff with pre-existing medical conditions (e.g. diabetics, hypertensive patients, AIDS patients, Cancer patients, etc.), pregnant women, and those above 50 years of age are provided with additional protection against COVID-19. Depending on the nature of the study, this may entail having such vulnerable groups not go into the field but perform other research duties where they have less exposure.

All Research Ethics Committees must ensure that at a minimum, a document signed by the Principal Investigator detailing all measures put in place to protect both the research team and the research participants against COVID-19 as per current Zambian and international guidelines is attached to the Study Protocol before they can grant ethical clearance.

2. *Research methodologies be adapted to meet current public health measures against COVID-19*

Whenever possible, remote data collection should be used. The Principal Investigator must explain in every case why remote data collection cannot be undertaken.

3. *All research budgets must have a specific budget line to meet costs of protecting researchers and research participants*

All health research conducted during the COVID-19 Pandemic or any other public health emergency must have a budget line dedicated to measures aimed at protecting both the research team and the research participants against contracting the infectious disease

4. *Research should be conducted only if it does not impede emergency response efforts*

Research should not be conducted if it can be expected to take away personnel, equipment, facilities, and other resources from those required for outbreak response by the Zambian government or its partners. In addition, resources allocated to research must not take away from routine health care and public health services.

3. *Research activities should be well coordinated to ensure synergies and be responsive to the evolving health needs*

Research projects should be coordinated nationally and/or internationally to avoid wasteful duplication and underpowered studies, and to ensure that priorities and activities are consistent with response efforts. It is for this reason that the National Health Research Authority developed the COVID-19 Research and Innovation Plan to mount a coordinated national health research response. Rapid sharing of information generated during research — subject to ethical requirements such as maintaining the confidentiality and privacy of personal information—with those participating in response efforts can also help strike an effective and mutually beneficial balance between research and response. The wellbeing of all Zambians must be prioritized

4. *A status report for all research activities should be submitted to the National Health Research Authority*

ahead of all research activities.

To effectively coordinate research efforts in line with guidance No. 5 above, a status report for all research activities should be submitted to the National Health Research Authority as per reporting template recently sent to all researchers and research institutions and attached here for ease of reference. The National Health Research Authority will also hold monthly COVID-19 virtual scientific meetings to facilitate sharing of research information.

5. *We strongly encourage collaborative research partnerships in emergencies to prioritize outbreak response challenges*

Recognizing the crucial role that international collaborations play in research, Partners should jointly prioritize the challenges faced in the outbreak, determine the research projects that will best address those challenges, conduct the research (including recruiting participants), and ensure that the research ultimately benefits Zambians in general and specifically the participating community by, for instance, ensuring health systems themselves learn from research results so that they may be better prepared for future emergencies.

To better ensure that research is responsive and sensitive to local realities, needs, values, and cultures, it is imperative that communities and researchers from local contexts be engaged at all stages of research, if feasible. Partnering with local researchers can also help build relationships and trust, which can go a long way in promoting effective research and response. Collaborations should adhere to the requirements for fair research collaborations such as those proposed by the Council on Health Research for Development (COHRED) and in line with the National Health Research Act No 2 of 2013 of the Laws of Zambia.

6. *Risk Communication and Community engagement*

Research during an emergency requires fair and meaningful community engagement and inclusive decision-making. The most inclusive level of engagement is one in which local stakeholders are not only consulted but also take part in decision-making processes with respect to research design, implementation, and evaluation. This involves inclusive and accountable decision-making. It requires that all reasonable steps are taken to ensure that all those concerned, including those who are the most vulnerable and marginalized, are included. The Principal Investigator must ensure that research utilizes and contributes to the strengthening of existing community engagement networks in emergency response.

7. *Requirements of informed consent in for research conducted during public health emergencies*

Individual informed consent is a fundamental ethical requirement for research. Prospective research participants must be able to weigh the risks and benefits of participation. This can be particularly challenging in a public health emergency because of uncertain risks and the perception that any research-related intervention must be 'better than nothing'. Consequently, researchers and review bodies have an obligation to ensure that research activities do not proceed unless there is a reasonable scientific basis to believe that the study intervention is likely to be safe and efficacious and that risks to participants have been minimized to the extent reasonably possible. Cultural and linguistic differences, as well as confusions about the dual role of the clinician/researcher, may be heightened for research conducted in this context, and so processes for obtaining informed consent, including the wording of documents and methods of obtaining and recording consent, should be developed in consultation with local communities. Finally, researchers should inform potential participants about the circumstances under which their data or samples might be shared. The National Health Research Authority through the National Health Research Ethics Board (NHREB) will work with Research Ethics Committees to standardize the Consent Form and Information Sheets for Research Participants during emergencies.

8. *Sharing of Research Benefit, Data and Samples during public health emergencies*

Researchers and research funders should provide individuals and communities who participate in research with access to any benefits that result from their participation. Where interventions are found to be safe and effective, those interventions should be made available to local populations as soon as possible, including via monitored emergency use of unregistered and investigational interventions (MEURI) when appropriate. All efforts should be made to provide fair access for all to the benefits of research conducted during emergencies.

In addition to informing the NHRA, participants and stakeholders should be fully informed about the collection, storage, future use, bio-banking and where permissible the export of human biological material. Researchers generating information that has the potential to aid response efforts have an ethical obligation to share that information as soon as it is quality-controlled for release (e.g., peer-reviewed). To ensure the greatest impact of the research, information should be shared with those involved in response efforts in addition to research participants, affected populations, and the global community. Researchers should share this information without waiting for publication in scientific journals through engaging the NHRA or at platforms such as the NHRA's monthly COVID-19 or the general quarterly scientific dissemination meetings.

It is the duty of the Principal Investigator to ensure that ALL the measures above are complied with.

Further reading:

1. World Health Organization. (2016). Guidance for Managing Ethical Issues in Infectious Disease Outbreaks.
2. Nuffield Council on Bioethics. (2020). Research in Global Health Emergencies: Ethical Issues
3. Council for International Organizations of Medical Sciences. (2016). International Ethical Guidelines for Health-Related Research Involving Humans
4. Ezekiel J. Emanuel, David Wendler, Jack Killen, Christine Grady. (2004). What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research. The Journal of Infectious Diseases, 189(5): 930–937. https://doi.org/10.1086/381709
5. World Health Organization. (2020). Ethical standards for research during public health emergencies: distilling existing guidance to support COVID-19 R&D. World Health Organization. https://apps.who.int/iris/handle/10665/331507