



COLLEGE OF MEDICINE

The Principal

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TO: RESEARCHERS

FROM: COMREC CHAIRMAN

DATE: WEDNESDAY, 1st APRIL, 2020

SUBJECT: COMREC COVID_19 RESEARCH GUIDELINES

We write to researchers whose studies were approved by the College of Medicine Research and Ethics Committee (COMREC), with an announcement about research involving human participants. COMREC would like to provide basic guidance on how studies should proceed given the realities of the current situation (Covid19).

The guidelines presented hereunder are based on the primary principle that studies should maintain their **scientific validity, protecting staff and research participants**. All suggested changes by studies should be communicated in form of amendments to COMREC. The guidelines include:

1. Studies that involve many participants in person at the same time should be stopped or where possible revisit the process to minimize the number of participants. Ideally, only one participant at a time in a space.
2. Explore options of research methodologies that do not compromise the validity of the science that require no direct participant interactions.
3. In the event that there is an active Covid19 pandemic in Malawi and there is a surge in demand for Covid 19 health services, researchers who are health workers are encouraged to suspend research activities so as to contribute to the prevention, treatment and mitigation efforts of the pandemic.
4. Studies are encouraged to visit research participants, provided they safeguard the safety of researchers, the participants and research scientific validity than to bring participants to the clinics to avoid unnecessary congestion. Researchers should adhere to all preventive measures as advised by WHO and the national guidance.

5. Changes to methodology should not include activities that are not ethically appropriate to conduct through remote interaction.
6. All studies should comply with the disaster emergency rules and guidelines of the country
7. Studies that have been providing or will be providing health commodities (vaccination / medications or medical device) that have potential for participants to experience adverse events, researchers should make sure that they continue to make follow ups. This could be made through phones or other possible electronic means. In the advent that there is need for the participants to be provided with in person medical care, researchers should make all necessary preventive measures to protect themselves and the participants from potential infection. This could include deployment of a vehicle (ambulance allowed to travel even in lockdown) to reach the participants
8. Researchers / studies must document all protocol deviation and violations (fully explained) that occur due to the measures put in place.
9. Researchers should submit amendments if they decided to include in their study elements that are COVID 19 related. These changes to the protocol could be in form of expanding or reducing scope of work or new objective in relation to COVID-19.
10. During the time that studies will be voluntarily postponed those that cannot practically be implemented in this Covid 19 environment, COMREC will freeze the time, thus that period will not count, and therefore protocol expiry period will be extended accordingly.
11. The freezing of time will include for studies that depend on reason, to wait for as long as a year until when the season is appropriate.
12. COMREC will not expect amendments or updates from studies that are not affected in any way by the COVID 19 e.g. lab based studies provided there is continuous access to supplies
13. If studies cannot guarantee that they would have reagents / commodities to monitor participants, they should stop recruitment.
14. There is potential for an increase in public transport costs due to public health measures (such as 3 passengers in a minibus). Studies should be revise their compensation amounts to make sure participants are paying for their travel to the study sites.



Eric Umar, PhD

COMREC Chairman