**DODOWA HEALTH RESEARCH CENTRE INSTITUTIONALREVIEW BOARD GUIDELINES FOR RESEARCHERSDURING THE COVID-19 PANDEMIC**

On 11th March 2020, the World Health Organization declared the novel coronavirus (COVID-19) a global health pandemic. Ghana, like other countries around the world has been affected. The nature of the current pandemic has necessitated several public health measures which have implications for the conduct of research with human participants.

The Dodowa Health Research Centre Institutional Review Board (DHRCIRB) which has the mandate to review the ethical merit of research protocols wishes to provide the following guidance on how research should proceed under the current COVID-19 pandemic. The committee acknowledges that the conduct of research during this pandemic is an ethical imperative and an essential part of the response measures[[1]](#footnote-1). COVID-19 is also happening within the context of already existing healthchallenges which require further research. Research on COVID-19 will also provide better understanding of the nature and transmission of the virus, identifying candidate vaccines and treatments and addressing the psychological and socio-cultural challenges associated with the diseases and the implications of current response measures.

The principles underpinning these guidelines are to ensure that research is conducted in a manner that protects the *safety*, *rights* and *welfare* of research participants as well as study teams.

This guidance document relates to three categories of studies:

* Approved protocols for ongoing studies
* New submissions (new protocols)
* Covid-19- related research protocols

**Approved (Ongoing) Research**

1. All approved research projects involving direct contact with research participants i.e. face to face interviews, focus group discussions, group activities should temporarily cease and put in measures to adhere to current national directives on social distancing and to protect the safety of participants.
2. All approved projects whose suspension will expose study participants to extra risk or danger, should communicate these risks via email to the DHRCIRB to discuss how best to address them.
3. Principal investigators are advised to review their current research methodologies and determine if a change in methodology is likely to minimize contacts with research participants.
4. In exploring options for updating research methodologies/procedures, researchers should ensure that they do not compromise the scientific validity of the study.
5. No study methodology already approved by the DHRCIRBshould be changed or altered and implemented without prior approval from the DHRCIRB in writing.
6. All protocol amendments including those that may seek to include COVID-19 related objectives should be submitted to the IRB for review before implementation.
7. If the protocol demands that participants are contacted, researchers are encouraged to continue to contact participants provided they are adequately protected.
8. Researchers should adhere to all preventive measures of protocols as advised by WHO and the national directives on COVID-19.
9. If for some reason, the study is stopped or voluntarily postponed as it practicallycannot be implemented in this COVID-19 environment and the period exceeds the 12-months granted by the DHRCIRB, the Principal Investigator (PI) should submit a protocol for renewal of the approval before the expiry date.
10. Researchers are to note that NO STUDY PROCEDURES can be carried out during the period that study approval has expired. Researchers are required to notify the DHRCIRB of such situations. Researchers are therefore advised to submit renewed applications at least 3 months before the expiry date to avert any lapse in data collection period.
11. 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 the participants and study team(s) from potential infection with COVID-19to and from study site.
12. The current COVID-19 pandemic and public health measures in Ghana are likely to increase the cost of travel to study sites. Study teams are therefore advised to revise their reimbursement amounts accordingly to ensure that participants are adequately reimbursed for their travel to and from the study sites. These revisions should be submitted as an amendment in the protocol and Informed Consent Form for DHRCIRB approval.
13. The DHRCIRB must be informed in writing of all changes made in a prior approved protocol before they are implemented.

**New Protocol Submissions**

The DHRCIRB will continue to receive and review new protocol submissions that can be conducted within the current pandemic and public health restrictions.

1. All existing guidelines and requirements for submission are still valid for new protocol submissions.
2. All new submissions will now be submitted electronically by email to the Administrator of the DHRCIRB until further notice.
3. All new research proposals/protocols should take the current Covid-19 pandemic and public health measures into consideration by ensuring that the proposed research and methods for data collected can be conducted in a safe environment that also adheres to national directives on social distancing etc.
4. All new applications should include under the section on ethical considerations, the potential risks of conducting the study under the current circumstances and how these risks would be mitigated.
5. The methods for data collection could include methods that limit direct contact with research participants and could include the use of online surveys or telephone interviews.
6. The use of alternate methods of data collection such as online survey and telephone interviews should be scientifically valid and also address ethical issues related to privacy and data protection.
7. All new protocols should include risk communication and public education on national preventive directives on COVID-19. These measures should be included in the research protocol and submitted to the DHRCIRBfor approval.

**Covid-19 related research**

* The DHRCIRBrecognizes that research is intrinsic to effective response to the COVID-19 pandemic and would endeavor to support and accelerate the review of all COVID-19 related research protocols.
* All such protocols should follow the requirements for protocol submissions including the recommendations outlined above.

**Other Key Considerations**

1. Protecting study participants
   1. All participants should undergo hand washing with soap and running water or sanitise their hands with alcohol-based hand sanitisers on arriving at study site(s).
   2. All participants should wear or be advised to wear face mask to and from study site(s) when they leave home to the study site.
   3. Participants should be taught how to wear, remove and care for the reusable facemasks. All participants without a face mask upon arrival at the study site should be provided with one and also advised to keep it on until he/she gets home and to properly dispose of it at home.
   4. The facemasks should be provided by the study teams at no cost to participants. Where applicable, provide all participants with a facemask to be used when coming to the study site for their next study visit.
   5. Physical distancing should be maintained during the study visit.
   6. Participants should comply with any restrictions to movements imposed by national or local covid-19 response team (e.g. self-quarantine, isolation, lock down)
2. Protecting Research Study Teams:
   1. The preventive measures outlined above also apply to study teams.
   2. All researchers must ensure adequate protection by practicing good personal hygiene through regular hand washing, the use of sanitizers, protective gloves and wearing facemasks.
   3. Social/physical distancing should be observed keeping at least 6ft between people.

**Note: The guidelines must be complied with during training of the research team, transportation of study participants (where applicable) and all other study procedures.**

This DHRCIRB Guidelines are online with other internationally[[2]](#footnote-2) accepted guidelines on general ethical reviews and becomes effective 1st April, 2020.

1. <https://academic.oup.com/jid/article/189/5/930/810459>;<https://cioms.ch/>;<https://apps.who.int/iris/handle/10665/250580>; <https://www.nuffieldbioethics.org/publications/research-in-global-health-emergencies> [↑](#footnote-ref-1)
2. 1.Nuffield Council on Bioethics Report. Research in global health emergencies: Ethical issues, 2020

   <https://academic.oup.com/jid/article/189/5/930/810459>;<https://cioms.ch/>;<https://apps.who.int/iris/handle/10665/250580>; <https://www.nuffieldbioethics.org/publications/research-in-global-health-emergencies> [↑](#footnote-ref-2)