UNIVERSITY OF NAIROBI (UoN)
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH-UoN ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: ttps://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC

KENYATTA NATIONAL HOSPITAL (KNH)
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

KNH-UON ERC- GUIDELINES ON CONDUCT OF RESEARCH DURING THE COVID-19 PANDEMIC

Introduction

Given the highly infectious nature of SARS-Cov-2 and the rapidly changing circumstances around COVID-19 containment, mitigation and management strategies in Kenya, the priority for all study activities should be to uphold public health obligations, and continue care of the research participants while guaranteeing the safety for the participants, the research team, and the general public. This is the obligation of the Principal Investigator (PI) working together with the other members of the research team. The scenario calls for a need to revise standards related to research interactions with human research participants with a strong push towards interacting **remotely.**

General considerations

1. ***Adherence to COVID-19 related public health directives:*** Researchers should remain aware of, and abide by all applicable COVID-19 related public health directives, policies and recommendations as issued by the World Health Organization, Ministry of Health or other Kenyan government agencies on what to do in case they encounter participants reporting **possible COVID-19 exposure or symptoms during a study visit or** those particularly vulnerable to COVID-19 disease.

2. ***Public Health and Clinical Activities*****:** Actions taken for public health or clinical purposes as part of the COVID-19 prevention, control or management are not considered research procedures and therefore do not require KNH-UoN ERC approval before being implemented. For example, mandatory clinical screening procedures in health facilities as directed by Ministry of Health or other designated public health authorities for purposes of identifying, monitoring, assessing/investigating or managing the COVID-19 outbreak, and sharing of such screening results with the participants and public health authorities does not require ERC approval.

3. ***Research changes made to mitigate risk of COVID 19 disease transmission*****:** - Researchers will need to implement changes to previously approved research to mitigate risk of COVID-19 disease pandemic.

4. ***Essential research visits or procedures*****:** -
   i. A study procedure or visit is deemed essential if it is required to ensure participants' health, safety, or wellbeing. Such procedures include administration of certain types of study interventions, safety evaluations and management of serious adverse events or laboratory tests to monitor possible adverse effects of drugs.

ii. The determination of what constitutes essential study visit or procedure shall be made in line with the current public health guidance regarding the COVID-19 pandemic in Kenya.

iii. Research visits should continue remotely as much as possible. In the absence of feasible remote options for essential visits or procedures, face-to-face interactions may continue **but investigators must** adhere to current public health guidelines to reduce COVID-19 exposure to research participants and staff.

iv. The PI shall be responsible for providing this service in the safest way possible, based on good clinical practice and optimal social distancing. The following guidance should be considered:

a) Immediately before the face-to-face visit, the participants should be remotely screened for symptoms of respiratory illness and other key defining symptoms of COVID-19 disease such as fever, cough, and shortness of breath or difficulty in breathing as well as possible recent exposure to individuals with COVID-19 disease. Participants with possible exposure or symptoms suggestive of a respiratory disease should not be invited for face-to-face visits/procedures until COVID-19 has been ruled out. Such participants should be immediately referred to the Ministry of Health for further diagnostic procedures and possible isolation, as necessary.

b) All research staff who conduct face-to-face visits or procedures with participants should, on a daily basis, be screened for COVID-19 exposure and symptoms including daily temperature checks. Only staffs who are symptom-free with no history of exposure to COVID-19 should take part in face-to-face interactions.

c) At the site of the face-to-face visits/procedures, appropriate infection prevention control measures should be ensured as follows:

i. Temperature checks for all participants and other individuals arriving at the research site using a non-contact thermometer should be taken.

ii. Hand-washing station and hand sanitizers for all to use should be availed.

iii. Avail 3-ply face masks for participants and research staff to use during the face-to-face interactions

iv. Physical distancing of minimum 1.5 metres in the waiting room and procedure rooms should be maintained.

v. Staff should use appropriate personal protective equipment as recommended in the MOH infection prevention and control (IPC) guidelines when conducting close-contact or invasive procedures and handling bio-specimens.

vi. Staff should be trained on appropriate cleaning and infection control procedures necessary to mitigate COVID-19 spread at study site.

5. ***Contingency Planning:***

a. Each research study team should have a contingency plan in place to continually assess the effect of any disruptions arising from the research protocol changes which might impact on the safety of their research participants.

b. All approved studies that require face-to-face interactions must submit an amendment to the KNH-UoN ERC indicating measures taken to minimize COVID-19 exposure to research participants, staff and the community.

c. Study visits and procedures should be conducted remotely through phone-based or internet-based methods using KNH-UoN ERC approved tools that define when, how, where, why and by whom each online process will be carried out.

Responsibilities of Principal Investigator

1. KNH-UoN ERC -approved studies where study procedures such as consenting and data collection are to be conducted remotely can continue and submit a notification in case of changes with regards to adherence to MOH COVID- 19 guidelines.
2. KNH-UoN ERC approved studies that had indicated in their protocols that they would conduct in-person study visits or procedures should submit an amendment to request the change from in-person to remote visits/procedures as necessary.
3. Research requiring ongoing in-person visits/procedures /interactions with participants should submit an amendment / modification to KNH-UoN ERC indicating the measures that shall be taken to minimize risk of COVID-19 exposure to participants and staff. KNH-UoN ERC approval is required before effecting the changes.
4. If there is need to modify the schedule of study procedures to accommodate COVID-19 related measures, this should be done through an amendment application to KNH-UoN ERC.
5. Participants should promptly be informed of cancellations of study visits and reasons why, and assured that they would be contacted if the visits are rescheduled. The cancellations and re-scheduling of visits should be submitted to ERC as notifications.
6. If a study has been or needs to be temporarily paused to fulfill COVID-19 related containment measures, the following should be considered:
    a. If temporarily halting research activities has or will have no effect on the safety or welfare of participants, this should be reported as a notification to ERC.
    b. If temporarily halting research activities could result in increased risk of harm or affect the welfare of participants, the researcher must submit a protocol amendment for ERC review and approval.
    c. For a study that had temporarily halted research activities and noted increased risk of harm / negative effect on the welfare of participants, the researcher must complete a protocol violation report and submit a detailed declaration of the risk /harm suffered including any mitigation on the same
    d. The researcher should clearly indicate the short- and long-term effect(s) that the pausing of research activities could have on research participants.