Research/ethics review committee members Interview Guide

A: normal process of ethics review

1. Introduction: tell us a little bit about the Ethics Review Committee/Research regulation/review committee that you are a member of, and your role in the ERC/Research regulation/review (how long has the committee existed? How was it created? How does it relate with National Research Authority and other research regulators in the country? How does it link with other ERCs within East Africa, Africa and outside Africa?)
2. Under normal circumstances (pre-covid19), what process does the committee follow in reviewing protocols, how long do these usually take? Prompt for different types of protocols (Challenge studies, phase I, II and III 3 clinical trials, social science protocols, multi-country studies etc)
3. What types of challenges does the committee normally face in the routine review processes; how are these handled (e.g. new research design, reviewers to review, workload etc)?

B: Review of COVID19 related protocols: *On 13th March 2020, the first case of COVID19 was reported in Kenya:*

4. **Preparation**: in what way did the committee prepare to handle the workload of protocol reviews for a) COVID-19 related protocols b) non- COVID-19 protocols? (Prompt: what was prioritized, and why? How were these decisions made (ie who was consulted, when and to what end?)
5. What were some of the memorable experiences you went through at these initial stages, what challenges did you encounter, and how did you resolve these? what worked well? What didn't and why?
6. Now that you have gone over this initial phase, and COVID-19 has been in Kenya for a few months, what has changed in terms of review of protocols, (probe for the range and type of challenges? What is working well, and what is not working well? How are you coping?)
7. E*xpedited review:* rigorous protocol review during times of emergency is important, and feedback is expected within a very short time period (fast turn-around); how did/are you responding to this urgency for much needed research to inform response strategy?
    a. processes and procedures are being implemented to expedite review for the different types of studies. What does an expedited review process involve? (reviewers, documents, submission processes, turn-around time)
    b. What has worked well in this process, what has been the most challenging and why? How did you make the trade-offs?
    c. A number of International guidelines have been in place to anticipate and respond to ethics and scientific review during global health emergencies. How useful did you find such documents to be? Did you formulate your own guidance documents, how did you go about it? Who did you involve/ engage in the process? What is different in your guidelines?
    d. Over time, What types of review challenges have persisted, Why? how are you addressing these? How have found the communication with study PIs/ applicants for

ethics approval? (prompt if they understand the challenges faced by committees and how they respond to such challenges (eg. Adhering to new submission guidance, delays in protocol review etc))

e. Overall, how do you think the committee is/has performed with regards to a) covid19 related protocols ii) non-covid19 protocols iii) other functions of the committee

8. What support have you received from your host institutions/government during this period to cope with the emerging challenges (if any); what do you think of this support (e.g. is it in line with what you need? OR if not support yet, what are your expectations from your host institutions and/or government?)
9. On reflection, what are some of the important lessons that the committee has learnt? How might you accommodate these lessons moving forward? (probe: under the 'new normal' and in times of public health emergencies, coordination/links between ethics committees – county/institutional/national/external?
10. Any other recommendations?