

In-Depth Interview Guide for the Effect of Public Health Emergencies on the Research Regulatory Systems: A Qualitative Study of COVID-19 in Uganda- REC Chairpersons, REC Members and Researchers

Introduction

The Uganda National Council for Science and Technology (UNCST) in collaboration with the National Drug Authority, the Uganda National Health Research Organisation, Jimmy University and University of Oslo is implementing a project entitled: “Strengthening Clinical Trial Regulatory and Ethical Review Oversight in East Africa (ACCESS2 AFRICA)”, funded by the European and Developing Countries Clinical Trials Partnership (EDCTP).

One of the objectives of ACCESS2 AFRICA is to strengthen linkages between regulatory authorities and ethics review committees. In this regard, the UNCST would like to conduct a study that seeks to explore the effect of public health emergencies on the research regulatory system in Uganda, over the last three (03) years so that it can strengthen the research regulatory system preparedness and governance. We expect that completing this tool will not take more than 60 minutes. In case you have further inquiries about this exercise, kindly let us know by telephone on : **0772620279/ 0702620279**.

1. In your opinion, how did the COVID-19 research guidelines support the streamlining of REC operations or conduct of research during the pandemic? How did the policies support the operations or affect the operations? How did the researchers adhere or comply with the research regulations?

2. As a member of the REC/Researcher, what REC Operations were implemented during the pandemic?
3. What are some of the challenges experienced during implementation of the operations?
4. As a member of the REC/researcher, how did you cope with REC operations during the pandemic? What coping strategies are implemented by the REC?
5. Do you think that COVID-19 guidelines had the information in the conduct and regulation of research during a pandemic? (Probe for how).
6. From your experience of the application of the National Research Registration Information Management System (NRIMS), share some of the challenges that you have encountered or observed?
7. How can the above- mentioned challenges be mitigated to ensure a successful usability of the NRIMS?
8. What do you think should be done by the regulatory agencies and RECs to improve the research online application?
9. What opportunities for the regulatory agencies and the RECs do you think COVID-19 pandemic brought on board?
10. What would you like to see change in the regulatory agencies and REC operations after the COVID-19 pandemic?
11. Are there any other important issues that you would like to share that would help to enhance the regular REC operations during public health emergencies?

We have now come to the end of the interview.

Thank you very much for taking time to respond to these questions and your participation in this exercise.