THE AGA KHAN UNIVERSITY

Faculty of Health Sciences
Medical College

Ref: 2024/ISERC-159 (v3)
January 23, 2025

Dr Moses Kachama – Principal Investigator
Postdoctoral Fellow
Brain and Mind Institute
Aga Khan University, Nairobi

Dear Dr Kachama, and team,

Re: Digital Mental Health Intervention for Young People in Kenya: Formative Research on Prospects, Challenges and Opportunities.

The Aga Khan University, Nairobi Institutional Scientific and Ethics Review Committee (ISERC), is in receipt of your protocol uploaded on Infonetica. The ISERC has reviewed and approved this project *{as per attached official stamped protocol and attachments - version Ref*: 2024/ISERC-159 (v3). You are authorized to conduct this study from **January 23, 2025**. This approval is valid until **January 21, 2026,** and is subject to compliance with the following requirements;

1. The conduct of the study shall be governed at all times by all applicable national and international laws, rules and regulations. ISERC guidelines and Aga Khan University Hospital policies shall also apply, and you should notify the committee of any changes that may affect your research project (amendments, deviations and violations)
2. Researchers desiring to initiate research activities during COVID-19 pandemic must comply with the COVID-19 SOPs for Research as well as submit to the Research Office a Request Form to Initiate, Reinstate or Continue Research During COVID-19 Pandemic.
3. **Prior** to human subjects enrolment you must obtain a research license from the National Commission for Science, Technology and Innovation (NACOSTI), *where applicable*, site approvals from the targeted external site(s) and file the copies with the RO.
4. *As applicable*, **prior** to export of biological specimens/data, ensure a Material Transfer Agreement (MTA)/Data Transfer Agreement (DTA), is in place as well as seek shipment authority/permit from the relevant government ministry. Copies of these approvals, should be submitted to the RO for records purpose.
5. All Serious Adverse Events and the interventions undertaken must be reported to the ISERC as soon as they occur but not later than 48 hours. The SAE shall also be reported through the AKUHN quality monitoring mechanism(s) at Client Relations Department of the Chief of Staff's Office.
6. All consent forms must be filed in the study binder and where applicable, patient hospital record.
7. Further, you must provide an interim Progress Report Form **60 days before expiration** of the validity of this approval and request extension if additional time is required for study completion; as well as submit the completed Self-Assessment Tool -Monitoring Ethical Compliance in Research. You must advise the ISERC when this study is complete or discontinued and a final report submitted to the Research Office for record purposes.
8. The Aga Khan University Hospital management should be notified of manuscripts emanating from this work.
9. The principal investigator and the sponsor will be responsible for ensuring compliance with good clinical practice.

If you have any questions, please contact Research Office at AKUKenya.ResearchOffice@aku.edu or 020-366 2148/1136.

With best wishes,

Dr. Christopher Opio,
Chair - Institutional Scientific and Ethics Review Committee (ISERC)
Aga Khan University, (Kenya)
Copy: Co-Investigators