KENYA MEDICAL RESEARCH INSTITUTE

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Final Decision Certificate

This document certifies that the study:

"INSPIRE-Mental Health Project"

Principal Investigator: Dr. Kiragga, Agnes

Reference number: SERU4880

Was reviewed and received the following status:

"done"

Additional Comments: Final decision: **approved-major-mod-req**
Comments sent:
The KEMRI Scientific and Ethics Review Unit (SERU) acknowledges receipt of your online study submission on the RHinnO ethics platform.
The reviewers noted that the above-referenced study aims;
1. To analyze availability, accessibility, and quality of new and existing longitudinal mental health data from populations and clinical sources across diverse African populations through landscape review.
2. Develop a comprehensive Theory of Change framework that outlines the logical pathways and key drivers for achieving improved mental health outcomes in the African context.
3. To discover the prevalence and risk factors associated with depression, anxiety and psychosis in the African setting using secondary data.
4. To investigate the empirical evidence supporting the validity of psychosis screening tools in African settings.

using quality of life and/or disability-adjusted life years (DALYs).
6. To augment standard vocabularies for describing mental health in the African context, providing a culturally relevant framework for discussion and analysis.
7. To provide an interactive dashboard for estimating and characterizing mental health observations, offering a user-friendly tool for understanding and addressing mental health issues.
After careful consideration, the reviewers find that the following issues will require addressing before approval is granted:
1. General Comments
i. Please submit CVs for all the investigators. Only CV for Dr. Frederick Wekesa is attached.
ii. Please submit the ethics training certificates for all the investigators. Only ethics certificate for Bylhah Mugotitsa has been submitted.
2. Lay Summary;
i. Lay summary lacks details on the methodology, sites, study population, data collection, sample size and study duration. Kindly include
ii. The lay summary has some terms that are not lay such as psychosis, Observational Medical Outcomes Partnership Common Data Models which need to be elaborated in simple language. Please simplify
3. Abstract;
i. The abstract is too detailed and long. Kindly summarize the abstract to present a short background, the main objective, summarized methods, to include study design, sample size, data collection, data analysis, expected results and their application and dissemination. All other details including the Theory of Change should go into the methods section in the main body of the proposal
ii. There are citations on the lay summary which need to be removed.
iii. The budget is also not necessary on the abstract. Kindly remove
4. Literature Review;
i. There is no mention of Kenyan data on the prevalence of mental health disorders despite there being a number of publications (2016-2022) on the topic. Kindly include
ii. What is presented as review of literature should be combined with the section presented as introduction to present a clear background on mental health issues and references used appropriately to back up the statements.
5. Problem Statement;
i. The problem statement is too long and unclear. What is the problem that this project seeks to study and resolve at the end of it? What is the issue that needs to be researched on?
6. Research Justification;
i. Kindly provide a section on justification for the study to give a rationale for need to undertake the proposed study.
7. Study Objective; what is the main objective of the study? Please provide one main study's objective and indicate the other objectives as specific objectives.
8. Methodology;
i. The subject matter is interesting but the protocol needs a bit more detail

especially the methodology section
ii. How will the homesteads in the HDSS' be identified?
iii. There is need to provide details of the HDSS to be used and team leads for those sites listed as co-investigators.
iv. How were the sample sizes of 5000, 100 and 10 for the activities arrived at?
v. How much time will it take to conduct the household survey and FDGs.
vi. Where will the FGDs be conducted?
vii. Will participants be facilitated to attend (time compensation and transport reimbursement?)
viii. How long does the screening with the psychosis tool take? Where will this screening be done?
ix. What will happen to individuals who are identified to have mental health issues?
x. Mental health issues are associated with a lot of stigma what plans do you have for community engagement in the areas where the data collection will be done.
xi. What tools will the mental health expert use to screen for psychosis in the 100 participants? Provide further details.
xii. On page 21, section on household survey method needs to be separated from the in-depth interviews. Information on who will participate in the IDIs and how these will be selected is missing. Please include
9. Data Management;
i. Provide a section on data management
ii. On the section on data analysis, clearly state how both the quantitative and qualitative data will be analyzed. What software and version will be used for each dataset? How will the 2 sets of data be reported?
10. Ethical Consideration;
i. On ethical consideration, please summarize the section to state how this will be taken care of
ii. Correct ESRC to KEMRI Scientific and Ethics Review Unit (SERU)
iii. Ethical considerations section does not mention that consent will be obtained from study participants and head of homesteads. Kindly include this detail
11. Study Timeframe; please adjust the study timeline to reflect the current status quo.
12. Role of Investigators;
i. Co-investigator Eugene Kinyanda has not signed on the proposal forwarding form yet he is listed on the section on roles of the investigators.
13. Data Collection tools;
i. The data collection tools are lacking a heading/title thus difficult to link them e.g. page 42-44
ii. There's need to have translated versions of the data collection tools and the Informed consent forms to be able to take care of the needs of the different study participants
14. Dissemination;
i. The plan for communication of findings needs to include sharing of study findings

with the County Department of Health.

15. ICF;

i. PURPOSE OF STUDY - "The study aims to collect data on psychosis using screening tools that have been validated for use in African settings. The study aims to build a 'dashboard' - an online tool that presents our findings in a clear and visual/interactive way." The words psychosis and dashboard need to be simplified further. Mental health needs to be introduced to the participant.

ii. WHY HAVE I BEEN INVITED TO TAKE PART? "You have been invited to participate because you are a member of the Health and Demographic Surveillance System (HDSS) we are currently collecting data from. You have volunteered to collaborate with us on this initiative." At this point consent has not been provided so the use of the word "volunteered" is not appropriate.

iii. WHAT ARE THE BENEFITS OF MY PARTICIPATION? "We also aim for you to become more confident in delivering interventions that may assist your peers." What interventions?

iv. The ICF needs to describe the data collection tools and the duration it will take to collect the data/conduct the interview.

v. ICF needs to be translated to the local language or Swahili

vi. How will the tools be used on people who don't understand English as this is not an exclusion criteria. The inclusion criteria needs to be clearly listed.

vii. The ICF for the FGDs is missing

viii. There is need for an information sheet for the head of the homestead, as they will need to provide permission for members of their homestead to participate.

ix. SERU email on the ICF needs to be updated.

x. Will the participants be reimbursed for their time/transport? If yes, please provide the information both in the proposal and in the informed consent forms.

xi. Please indicate how long the informed consent process will take for each participant.

xii. Apart from the email provided, Please provide a telephone/mobile number for the principal investigator that the participants can use to reach out in case of any concerns.

Kindly address the issues raised and submit the revised documents before or on the (21 Days) December 07, 2023 to the SERU Secretariat via seru@kemri.go.ke and kemriseru18@gmail.com.

SERU committee will discuss and make a final decision on your study at the next available meeting; however, it is to your advantage to respond to the issues as soon as possible.

Yours faithfully,

ENOCK KEBENEI,
THE ACTING HEAD,
KEMRI SCIENTIFIC AND ETHICS REVIEW UNIT.