In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR COMMUNITY ENGAGEMENT, RECRUITMENT METHODS AND ADVERTISING FOR PARTICIPANT ENROLMENT

Document Control Schedule

Name of department:	**SERU**
Document Type:	**Management Procedure**
Document Ref:	**KEMRI/SERU/SOP/PI/CE**
Process owner:	**Head Compliance SERU**
Signature:	
Approved By:	**Head SERU**
Signature:	
Effective Date:	**October 18, 2017**

Controlled copy: Circulation authorized by the Head SERU.

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1. PURPOSE

The purpose of this SOP is to outline the requirements for Community Engagement, Recruitment Methods and Advertisement for participant enrolment.

2. SCOPE

The SOP serves to guide the P.I on what considerations to make when writing a protocol that entails community engagement and recruitment of participants.

3. INTRODUCTION

Principal Investigators need to ensure that the participants they enrol in their studies are not only representative of the target population but that they are recruited in accordance with the best practices outlined in ICH-GCP and the principles in the Current World Medical Association's Declaration of Helsinki.

4. TERMS & DEFINITIONS

4.1 Community engagement in research: is the investigator-led process of meeting with, sensitising communities and stakeholders (participating in research) of planned study activities and addressing any emergent issues affecting their well-being.

4.2 Community advisory board (often called a CAB): is a group of representatives of the general public frequently brought together by the Investigator to speak on behalf of the interests of the community with respect to planned research

4.3 Recruitment: all the activities designed to identify, assess eligibility of potential participants and obtain their approval to participate in research, having adequately informed them of all pertinent aspects of the study.

5. OBJECTIVES

To ensure that the research participants are well made aware of the research to be conducted.

6. INPUTS/RESOURCES

6.1 Personnel
6.2 Stationery and office equipment
6.3 Budget
6.4 SERU approval

7. EXPECTED OUTPUTS

7.1 Recruited participants

8. KEY PERFORMANCE INDICATORS

8.1 No of participants recruited

9. RESPONSIBILITY AND AUTHORITY

9.1 Investigator- ensure that Community Engagement, Recruitment Methods and advertisement for enrolment in study is done in an ethically acceptable manner and that materials and methods used in recruitment are approved by KEMRI SERU.

9.2 Community advisory board (CAB): - present the interests of the community with respect to planned research to the PI

10. DETAILS OF PROCEDURE

10.1 The PI defines his/her community engagement plan in the study protocol recruitment procedures. This documents relevant stakeholders, how potential participants will be approached, incentives, materials and advertisements to be used.

10.2 The PI uses his/her best judgement to determine the level of risk posed by the study and whether or not a CAB will be used in the study. SERU may revise the risk assessment and require the use of a CAB prior to approval.

10.3 The PI constitutes an active CAB for his/her research site to ensures there is active community engagement during study conduct for studies deemed by SERU to be of moderate to high risk.

10.4 Procedure for constituting a CAB

10.4.1 Consists of 8 to 10 persons resident in the geographical area where the research study will take place

10.4.2 Recommendations for persons to include

10.4.2.1 Vulnerable person e.g. persons with disabilities

10.4.2.2 Person who is suffering or has suffered from the health problem the study is investigating

10.4.2.3 A research literate individual (individual with capacity to read and understand research methods, standards, etc) such as retired teachers, nurses, military personnel etc.

10.4.2.4 Males and females who represent the age spectrum such as elders, middle aged persons and young adults. Minors are excluded.

10.4.2.5 Individuals who are fluent in the local language or are native to the study area.

10.4.3 The CAB determines the frequency of meetings in collaboration with the PI

10.4.4 One CAB may serve for multiple research studies

10.4.5 Though incentives and payments to CAB members do not require SERU approval, they should neither be coercive nor constitute an undue influence

10.4.6 Individuals who leave the CAB may be replaced using the above recommendations

10.4.7 The PI trains the CAB on various ethical principles and research methods at least annually.

10.5 Study participants should be made aware of the existence of a CAB.

10.6 Any material, incentives and avenues used for advertisement and recruitment of participants must be approved by SERU before it is used. This includes communication via text messages, social media advertisements, print and other mass media.

10.7 The PI ensures that all participants in the research study are adequately informed about pertinent aspects of the study (e.g. risks, benefits, alternatives, duration and objectives) during recruitment.

10.8 The P.I obtains informed consent/assent from participants in accordance with KEMRI SERU *APP SOP 6.0 General Requirements of Informed Consent and Documentation of Informed Consent*

10.9 Any changes made to recruitment material must be approved by KEMRI SERU before being put into use.

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk source	Mitigation
Community Engagement and participant Recruitment	Low participant recruitment and refusal to participate in research	Failure to use the right channels in participant recruitment	-Training the community in the importance of research. -Involving the community leaders in Research through regular meetings

11.2 Opportunities

Process	Opportunities	Action plan to maximise the opportunities
Community Engagement and participant Recruitment	Training the community advisory board.	Organizing regular meetings and trainings for CAB on sensitizing the community before research

12. REFERENCE DOCUMENTS

12.1 Internal References

12.1.1 None

12.2 External References

12.2.1 ICH GCP https://www.ich.org/fileadmin/Public.../ICH.../Guidelines/.../E6/E6_R1_Guideline.pdf

Helsinki declaration http://www.who.int/bulletin/archives/79%284%29373.pdf

13. ANNEXES

13.1 SERU format and content of an informed consent form
13.2 SERU format and content of an informed consent form for genetic studies
13.3 Process flow chart

ANNEX I: SERU_FORMAT AND CONTENT OF AN INFORMED CONSENT FORM

The level of language and syntax used should be appropriate to the age, comprehension and reading level of the study population. The use of legalistic phrases, scientific and medical terminologies should be avoided. Volumes, weights as well as scientific measurements should be expressed in meaningful scales (e.g. blood draws in numbers of teaspoonfuls, tablespoonfuls or proportion of a National Blood Services donation).

All consent documents must have a version number, date and stamped by the SERU Secretariat.

PROPOSED FORMAT OF A CONSENT FORM

Title of the Research Study:

Investigator(s) – Local and International Collaborators: Provide the name and institutional affiliation of all investigators on the study. List PI first followed by co-investigators.

Study location: Indicate where the study will be conducted.

Purpose of the Research: Briefly describe the purpose of the study.

Description of the Research:
The study you are about to participate in is (briefly describe the study). Should you agree to participate in the study, you will be asked to (summarize study procedures).

a. Provide a brief description of the proposed research as it will be experienced by the research participants. Interventions or procedures that are part of standard care and those that are research must be distinguished.
b. If specific testing (e.g. HIV testing, HLA typing) will be done as part of the research, this must be explained.
c. If the study participant is receiving any therapy prior to enrollment in the study and this therapy will or may be altered or discontinued as a result of participation in the study, this must be explained.
d. If randomization or sequential assignment is planned, this must be explained.
e. If blood will be drawn, the total volume (teaspoons **and** millilitre equivalents) must be indicated and a statement about the possibility of bruising or swelling while giving blood, or some other discomforts at the site where blood is drawn and that there may be minimal chance of infection should be provided. If other specimens (e.g. urine, stool, saliva etc.) will be collected, the study participants must be informed.
f. The frequency and duration of specific testing, as well as the duration of the entire study should be specified.

g. The study participants should be informed that any changes made to the study or should new information become available, he/she shall be so informed.
h. If future use of the research data beyond the current study is anticipated, this should be clearly explained. If the research data/samples are to be destroyed after the study is complete, study participants must be informed of the plan.
i. If any tests will be done at other locations, the study participants must be informed of the location where the testing will be done and the purpose for the tests. This information must also be reflected in the body of the research protocol.
j. If a questionnaire will be administered or interview conducted, a description of the questionnaire/interview, the length of time it will take to complete it must be provided; the participants must also be informed that they may choose not to answer any questions or withdraw at any time.
k. If data will be abstracted from medical records or from other confidential sources, this must be so described.
l. The study participants must be informed if a study involves videotaping, taking photographs or audio recordings.
m. If products of commercial importance may be developed from blood samples, DNA, RNA extracted, so state and describe the plans for benefit sharing.

Potential Harm, Injuries, Discomforts or Inconvenience, Risks:

a. If there is no known or known harm/risk to the study participants, this should be clearly stated.
b. If there is known or anticipated risk, this must be clearly enumerated.

Potential Benefits:

a. If study participants will not benefit or might benefit directly from participation in the study, this should be stated and the potential benefits should be described.
b. If the community in general or patients with a similar condition stands to benefit from the results of the study, this should also be explained.

Alternative Procedures or Treatments:

a. If there is no treatment alternative, the alternative to participation in the study is non-treatment and this should be explained.
b. If there is/are a treatment alternative(s), the alternative(s) should be identified and described.
c. If the research is not about a treatment, this section may be omitted.

Confidentiality:

a. No information that reveals the identity of any study participant should be released or published without consent.
b. If access is required by a sponsor, SERU or other health regulatory authorities for the purpose of monitoring the study, this must be explicitly stated.
c. The plan for maintaining confidentiality of research records and materials must be clearly explained.

Reimbursement:

a. Study participants or their parents/guardians can be reimbursed for loss of wages, transportation expenses and for their time. Under no circumstances should payment be offered for harm or discomfort.
a. It should be clearly stated that if the study participant withdraws from the research, that there will be appropriate pro-rated reimbursement, where applicable.
b. A token of appreciation may be presented after completion of the study, but this should not be mentioned in the research consent document but must have been indicated in the body of the study protocol.
c. Include specific information whenever study participants will receive an inducement.

Participation:

a. If there are parts of the research study in which a study participant may choose not to participate, this should be clearly explained.
b. Parents/guardians of study participants should be made aware that assent may be required from their child.
c. All study participants must be given a copy of the signed and dated consent form to keep.
d. The plan for referrals for further medical care or treatment should be explained, where applicable and clarify who will be responsible for the cost of such treatment.

Sponsorship:

In situations where a study may be terminated at the discretion of the investigator or the study sponsor even if the study participants are benefiting, there should be provision for discussing the next course of action with the study participants and/or procedures for orderly termination.

Contact:

a. For any questions or concerns about a study or in the event of a study-related injury, the contact person is the principal investigator and/or the principal investigator's representative who should provide his/her 24-hour contact telephone number. The physical address must also be provided.
b. For any questions pertaining to your rights as a research participant, the contact person is: The Head, SERU, P. O. Box 54840-00200, Nairobi; Telephone numbers: 020-2722541, 0717-719477; Email address: seru@kemri.org/serukemri@gmail.com

All data collected from you will be coded in order to protect your identity, if applicable. Only the research study staff will have access to the information. At the end of the study, there will be no way to link your name with your data (where applicable). Any additional information about the study will be provided to you including the final study results.

You are free to withdraw or refuse to answer any questions at any time without any consequences.

Should you agree to participate in the study, please sign your name below, indicating that you have read and understood the nature of the study, your responsibilities as a study participant,

the inconveniences associated with voluntary participation in the study and that all your questions and concerns concerning the study have been answered satisfactorily.

You will receive a copy of this signed consent form to take away with you.

_____ _____

Signature of Study Participant and Date Thumbprint of Study

Participant and Date

_____

Signature of Person Obtaining Consent and Date

_____

Signature of Witness and Date

ANNEX II: SERU_FORMAT AND CONTENT OF AN INFORMED CONSENT FORM FOR GENETIC STUDIES

Title of the Research Study:
Investigator(s) – Local and international collaborators: Provide the name and institutional affiliation of all investigators on the study.

Study location: Indicate where the study will be conducted.

Purpose of the Research: Briefly describe the purpose of the genetic study in a language that should be understandable to the study population.

Procedures: Briefly describe how sample collection will be done, who will handle the sample(s), the location and duration of storage of the samples and indicate whether the study participant may be contacted in the future about the sample and/or study results.

Risks and Benefits: Briefly describe the common risks associated with sample collection and describe any potential risk if the genetic information is disclosed, either intentionally or inadvertently.

Confidentiality: Briefly describe the mechanisms that will be used to protect unauthorized access to the genetic material or information derived from it and the plans to destroy the sample in the future. Indicate whether the sample may be withdrawn at a later date if a study participant refrains from participating in the genetic aspect of a study.

Coding of samples: The type of coding of a sample must be specified because a sample that is anonymized cannot be withdrawn in the future.

Commercialization: The study participant(s) must be informed if there could be a potential for commercialization benefit from the results obtained using their sample. If that be the case, it must be clearly stated how the study participant, family or community stand to benefit.

All other elements of informed consent apply
(Refer to Appendix I: Format and Content of an Informed Consent Document)

ANNEX 3: PROCESS FLOW CHART

Players	**Activity**	**Flow Chart**
Principal Investigator	PI defines his/her community engagement plan in the study protocol recruitment procedures.	
Principal Investigator	Constitutes an active CAB for his/her research site to ensures there is active community engagement during study conduct for studies deemed by SERU to be of moderate to high risk.	
Principal Investigator	Ensures that all participants in the research study are adequately informed about pertinent aspects of the study (e.g. risks, benefits, alternatives, duration and objectives) during recruitment.