In Search Of Better Health

K E M R I

STANDARD OPERATING PROCEDURE FOR GENERAL REQUIREMENTS OF INFORMED CONSENT AND DOCUMENTATION OF INFORMED CONSENT

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1. PURPOSE

This standard operating procedure (SOP) describes the steps for fulfilling the ethical requirements for developing the informed consent document, submitting it for SERU approval, and for appropriately obtaining the subject's informed consent.

2. SCOPE

This SOP covers all the processes and procedures required for an investigator to obtain informed consent from a study participant

3. INTRODUCTION

The ethical conduct of clinical investigations is based upon the voluntary consent of the subject who has been appropriately informed about a study's risks and benefits. It is the responsibility of the investigator to ensure that informed consent itself has been properly obtained from the subject or the subject's legal representative.

Informed consent is a continuous process that starts with the researcher's first contact with the individual (18 years of age and above) and continues until the study is complete or the participant withdraws. Any discussion of informed consent with the participant, the written informed consent and any other written information given to participants should provide adequate information to enable the individual make an informed choice about his/her participation.

Documentation of the informed consent process is required to establish that the subject was accurately and adequately informed and that no study-related procedures were initiated prior to obtaining informed consent. Informed consent is a process for information exchange that takes place between the potential subject and the investigator, before, during and sometimes after the study.

4. TERMS & DEFINITIONS

4.1 Informed consent: - A process by which a participant voluntarily confirms his or her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to his/her decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

5. OBJECTIVES

To ensure that the PI obtains informed consent from the participants.

6. INPUTS/RESOURCES

6.1 Personnel
6.2 Stationery and office equipment
6.3 Emails
6.4 Checklists

7. EXPECTED OUTPUTS

7.1 ICF
7.2 Record of received Application

8. KEY PERFORMANCE INDICATORS

8.1 No of complains submitted to SERU by research participants

9. RESPONSIBILITY AND AUTHORITY

9.1 Investigator- The principal investigator is responsible obtaining inform consent

9.2 Secretariat- The SERU secretariat receives the application, acknowledges receipt and assigns it to reviewers

10. DETAILS OF PROCEDURE

10.1 Requirements of Informed Consent

10.1.1 Principal Investigators (P.Is) are required to obtain informed consent from each prospective study participant unless SERU waives some or all of the elements of informed consent (Appendix F: Format and Content of an Informed Consent Document).

10.1.2 P.Is seek consent from adults [aged eighteen (18) years and above and from parent/guardian whose child is aged seventeen (17) years or below if the child will be involved in a research study].

10.1.3 The P.I provides the following to SERU:

10.1.3.1 A full description of the process for obtaining informed consent including the identification of those responsible for obtaining consent

10.1.3.2 Provision for comprehensive (without technical terms) written and verbal information to be given to the research participants, and, when appropriate, their legally authorized representatives (LARs)

10.1.3.3 A clear justification for the plan to include individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals

10.1.3.4 Provisions within the study that research participants will receive information that becomes available during the course of the study relevant to their participation

10.1.3.5 Provisions made for receiving and responding to enquiries, concerns or complaints from research participants or their representatives prior to and during the course of a research study.

10.1.3.6 Translation of all consent documents into Kiswahili and/or relevant local dialects; each translated consent document must be accompanied by a Certificate of Translation and back Translation

10.1.3.7 Provisions to ensure that if a participant or their LAR is unable to read, an impartial witness is present during the entire informed consent discussion

10.1.3.8 Assurance that after the written informed consent form and any other written information to be provided to participants, is read and explained to the illiterate participant or their LAR, and after the subject or the participant's LAR have orally consented to the participant's participation in the trial and, if capable of doing so, has signed and personally dated the informed consent form, the impartial witness signs and personally dates the consent form. (By signing the consent form, the witness attests that the

information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant or the participant's LAR, and that informed consent was freely given by the participant or their LAR.

10.1.4 The P.I may request the SERU committee to waive all or part of the requirements for documentation of informed consent, [and make provisions for oral consent to be obtained, and documented as oral consent] if the research meets the following criteria:

10.1.4.1 Criteria 1: The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. OR

10.1.4.2 Criteria 2: The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context (e.g., calling someone at home and asking everyday questions, survey at a shopping centre, mail survey, internet survey, etc.)

10.1.4.3 Other criteria that the P.I must meet for the waiver of documentation of consent to be granted:

10.1.4.3.1 The proposed plan for the protection of privacy is adequate.

10.1.4.3.2 The waiver will not affect the rights and welfare of the research participants.

10.1.4.3.3 The research participants will be given additional pertinent information after their participation.

10.2 Requirements of Informed Assent

10.2.1 Where a proposed participant is a minor [aged >12 years but <18 years of age] who is possessed of sufficient understanding to grant informed consent but is precluded from granting such consent solely on the grounds of age, the PI

obtains a written assent in addition to permission from a parent, guardian or any other legally authorized person in the place of a parent.

10.2.2 The P.I avails the following elements for the SERU committee to consider during its review of the assent process:

10.2.2.1 The procedures put in place for obtaining parental or guardian permission (consent) to have his/her child or children participate in the research. For those minors aged >12 years but <18 years, the language and syntax of the assent form may be written in a similar fashion as the parental or guardian permission form.

10.2.2.2 If the research proposed is determined to present greater than minimal risk and there is no direct benefit to an individual study participant, that provisions to obtain parental permission from both parents/guardians have been made unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

10.2.2.3 Provisions for the parental permission and child assent to be done in writing unless the SERU committee grants a waiver of documentation of the assent

The P.I may use the table below as a guide in deciding whether or not to enroll a child, aged >12 to < 18 years in research.

If Parent Says (YES/NO) to participate	If Child says YES?NO to participate	Can Child participate

10.2.3 The ethical standards required in obtaining informed consent shall apply to assent. (Clause 6.1)

10.2.4 The P.I may request the SERU committee to waive the requirement for obtaining assent from a child if any of the following conditions apply, in which case, consent from the parent(s) is sufficient:

10.2.4.1 The intervention stands to directly benefit the health and welfare of the child and is available only in the research setting.

10.2.4.2 The child is unable to provide assent due to age [twelve (12) years of age and below] or has a condition that does not allow them to give assent.

10.2.4.3 The research meets the same conditions for a waiver of informed consent in research involving adults.

10.3 Obtaining Consent from a Mature Minor

10.3.1 The P.I ensures there are procedures to ascertain that the mature minor demonstrates evidence of clear understanding of the requirements for the research they are consenting to participate in

10.4 Community Considerations

10.4.1 The P.I provides the following to the SERU Committee:

10.4.2 The potential impact and relevance of the research on the concerned communities from which the research participants are drawn

10.4.3 The steps taken to consult with the concerned communities during the course of conducting the research and in disseminating research findings are transparent.

10.4.4 The measures taken to preclude the influence of the community on the consent of an individual

10.4.5 The proposed community engagement process including public meetings such as chief's barazas, permission from the community elder or persons acknowledged as community representatives and where applicable, the establishment of a Community Advisory Board (CAB).

10.4.6 The extent to which the research contributes to capacity building, such as the enhancement of local healthcare systems and the improved capability of the community to respond to their health needs.

10.4.7 The provision for making available any successful trial product to the participating communities on completion of the research and sustainability of any intervention

10.4.8 The manner in which the results of the research will be made available to the research participants and the concerned communities

10.4.9 The consideration for cultural sensitivities and concerns

10.5 Obtaining Consent from Special Populations

10.5.1 The P.I gives exceptional consideration to protecting the welfare of particularly vulnerable groups, such as children, pregnant women, neonates, foetuses, homeless youths, decisionally impaired persons, internally displaced persons, economically or educationally disadvantaged persons, marginalized social groups or individuals with terminal illnesses or prisoners.

10.5.2 In addition, the P.I demonstrates that:

10.5.2.1 The objective of the proposed research is to obtain knowledge relevant to the health needs of the population under study.

10.5.2.2 The research question cannot be answered if the study is carried out among a less vulnerable group.

10.5.2.3 The study participants are explicitly told that they are taking part in research.

10.5.2.4 The requirements for obtaining and documenting consent are tailored to the needs of the individual from the chosen vulnerable group. .i.e. use of appropriate language, content of the consent/assent document and explanation of the procedures to be followed

10.5.2.5 The risks from procedures that do not proffer direct health-related benefit are justified by the benefit and are similar to those from routine medical or psychological tests.

10.6 Documentation of Consent

10.6.1 The P.I is required to document the informed consent process by use of a written approved consent form unless a waiver is issued subject to conditions laid out in Clause 6.1.4 above.

10.6.2 The consent form must be signed and dated by the research participant or research participant's LAR at the time of consent.

10.6.3 A copy of the signed and dated consent form is given to the person(s) signing the consent form.

10.6.4 When verbal consent is obtained from an illiterate research participant or an illiterate LAR, the SERU committee shall require the presence of an impartial witness to the oral presentation. The SERU committee shall review and approve the written summary of what is to be presented. This summarized approved version of the consent form should be signed by the impartial witness and the person actually obtaining the consent.

11. RISKS AND OPPORTUNITIES

11.1 Risks

Process	Risk	Risk source	Mitigation
Consenting and Assenting participants	Exploitation of research participants	Failure to follow the due process of Consenting	Train research assistants on the importance voluntary research participation

11.2 Opportunities

Process	Opportunities	Action plan to maximise the opportunities
Consenting and Assenting participants	Trainings on Consenting	Participate in trainings on the Consenting Process .

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

12.2.2 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.

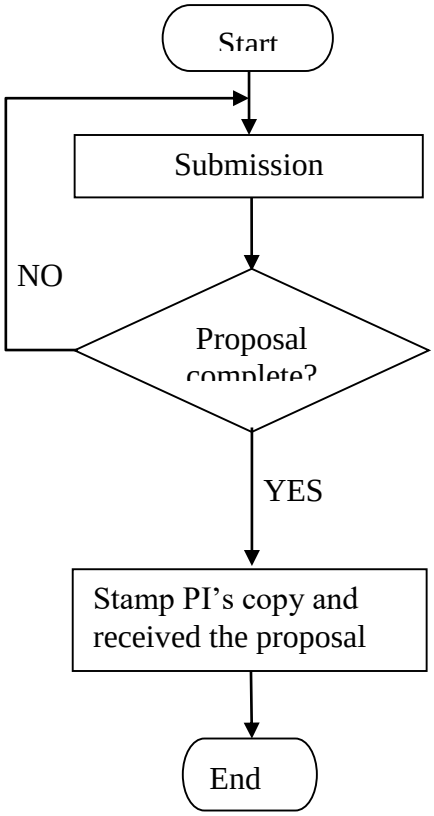
Confidentiality: Briefly describe the mechanisms that will be used to protect unauthorized access to the genetic material or information derived from it and the plans to destroy the sample in the future. Indicate whether the sample may be withdrawn at a later date if a study participant refrains from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

Players	**Activity**	**Flow Chart**
Principal investigator	Submits ICF	
Centre compliance Officer	Preliminary review to determine if it needs waiver or not as per criteria set.	
Centre compliance Officer	Stamps the documents and give the PI completed and stamped acknowledgement of receipt of the submitted documents to SERU	