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APPENDIX F: FORMAT AND CONTENT OF AN INFORMED CONSENT DOCUMENT

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 be signed and stamped by the SERU Committee Chairperson or SERU IRB coordinator.

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.

You are being asked to take part in a research study. The box below tells you important things you should think about before deciding to join the study. We will provide more detailed information below the box. Please ask questions about any of the information before you decide whether to participate. You may also wish to talk to others (for example, your family, friends, or your doctor) about this study, before agreeing to join.

Key Information for You to Consider(Not more than 500 words)
• **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to joint or if after you join, you decide to quit. [For challenge trials, this language will need to incorporate safety follow-ups] • **Purpose**. We are doing this research to [*provide a brief description of why the research is being conducted, no more than 2-3 sentences*]. • **Duration.** Your part of the study will last [*expected duration*]. • **Procedures and Activities.** We will ask you to [*briefly highlight the key research activities/procedures*]. • **Risks.** Most studies have some possible harms that could happen to you if you join. In this study, we expect that [*describe the most important risks. Consider those most probable and/or highest magnitude of harm*]. • **Benefits**. We expect some benefits from this study, as well. For you, we expect [*insert direct benefits, or if no direct benefit to subject state no direct benefit but the researchers hope to learn/gain xyz*]. For [future participants, people with similar conditions, etc] we expect [potential outcomes of research]. • **Alternatives.** Instead of participating, you could [*note appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. If there are no alternatives, state that, "Participation is voluntary and the only alternative is to not participate."].*

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

1. **Description of the Research:**

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. The participant should be informed that if; clinically relevant data arises as a result of his/her participation in the study, that information will be disclosed to them and under what conditions.

h. 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.
i. If any tests will be done at other locations, the study participants must be informed of the location 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 data will be abstracted from medical records or from other confidential sources, this must be so described.
k. The study participants must be informed if a study involves videotaping, taking photographs or audio recordings.

2. Human genome sequencing

The participant should be informed whether or not whole genome/exosome sequencing will be done on their bio-specimen. The participant should be informed that, through scientific tests of their whole genome, researchers can learn large amounts of information about them, identify genetic conditions which may make it more likely for them to develop a disease. They should also be informed that their whole genome sequence is unique to them, like a fingerprint and they can be identified by it.

Similarly, because of the large percentage of genes they share with their relatives, their relatives may also be identified by looking at the participants' genetic code.

3. **Storage of specimen, exportation of samples and further studies:** (Provide details about the samples to be stored or exported. Provide details about the destination of the samples and the nature of the studies that will be undertaken

a. If future use of the research specimen/data beyond the current study is anticipated, this should be clearly explained.

i. The participant should be informed if specimen/information to be used for future research will be shared with other researchers without additional consent with/without identifiers OR
ii. The participant should be informed if specimen/information to be used for future research will be shared with other researchers without additional consent as long **as identifiers have been removed** OR
iii. The participant should be informed **that additional consent** will be sought if specimen/information will be used for future research or shared with other researchers, with or without identifiers OR
iv. The participant should be informed that they can **decline** to have their specimen/information used or shared with other researchers for future research

b. If the research data/samples are to be destroyed after the study is complete, study participants must be informed of the plan.
c. If products of commercial importance may be developed from bio-specimen (blood samples, extracted DNA and RNA)/information, state and describe the plans for benefit sharing.
i. The participant should be informed if sample/information may be used for commercial profit even if identifiers are removed and that the participant **will share** in the commercial profit
ii. The participant should be informed if sample/information may be used for commercial profit even if identifiers are removed and that the participant **will not share** in the commercial profit.

4. 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.

5. 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.

6. 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.

7. 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, ERC 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.

8. 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.

b. It should be clearly stated that if the study participant withdraws from the research, that there will be appropriate pro-rated reimbursement, where applicable.

c. 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.

d. Include specific information whenever study participants will receive an inducement.

9. 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.

10. 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.

11. 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 rights as a research participant, the contact person is: The Committee Chairperson, KEMRI Scientific and Ethics Review Unit, P. O. Box 54840-00200, Nairobi; Telephone numbers: 020-2722541, 0717719477; Email address: seru@kemri.org

(The participant should be informed about and given signature options for consent)

(Signature blocks for participant and individuals administering consent must be part of all forms. Other signature blocks will be included when appropriate, as when the research study involves children, surrogate consent etc.)

12. Consent and signature options: (Write a statement of consent and give signature options and a thumbprint for illiterate study participants. The thumbprint will require a witness of an independent person outside the study team

……I agree for my specimen/information to be used for future research and shared with other researchers without my additional consent with/without identifiers
……I agree for my specimen/information to be used for future research and shared with other researchers without my additional consent as long as identifiers have been removed
……I agree for my specimen/information to be used for research or shared with other researchers with or without identifiers with my additional consent
……I do not agree for my specimen/information to be used for future research or shared with other researchers with or without identifiers

(*Required for future use*)Please initial the sentences that reflect your choices, and then sign below:

_____ I do not authorize the storage of data collected as a part of this study for use in future research studies.

_____ I authorize the storage of data collected as a part of this study for use in future research studies.

With regard to future research studies done on stored data that has a link to my personal identity.

_____ I do not wish to be notified by investigators in the event of research findings of possible importance to my family members or myself.

_____ I wish to be notified by investigators in the event of research findings of possible importance to my family members or myself. I agree that my current principal investigator may use any appropriate identifier (Social Security Number, country ID number, etc.) to locate me in the future.

SIGNATURE OF PARTICIPANT

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Permenent Address of Participant

(*Use the following signature blocks for representative, parents, and guardians, only if applicable****)***

Your signature below indicates you are legally authorized to act on behalf of the participant, and have read this document. You will receive a copy of this document. *(The Principal Investigator is responsible for confirming that an individual is a Legally Authorized Representative based on local and state laws.)*

SIGNATURE OF LEGALLY AUTHORIZED REPRESENTATIVE

_____
Printed Name of Legally Authorized Representative

_____
Relationship to the Participant

_____ _____
Signature of Legally Authorized Representative Date

(Remove the witness signature if this study is conducted under ICH GCP. Determine if your institution requires witness to the entire consent process or only witness to the final signature.)

SIGNATURE OF WITNESS TO CONSENT/CONSENT PROCESS
(This individual can be a relative of the participant, but cannot be an individual involved with the research study.)

_____
Printed Name of Witness

_____ _____
Signature of Witness Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date

SAMPLE CONSENT FORM

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).
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