**General Information**

* The level of language and arrangement of words and phrases 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.The technical terms can be used whenever necessary (for example when working with participants who are experts) and defined or simplified to enhance comprehension.
* Ensure you carry out the Test of Understanding to confirm that participant has comprehended the contents of the consent form as appropriate.
* Volumes, weights as well as scientific measurements should be expressed in meaningful scales (e.g. blood draws in numbers of teaspoonfuls, tablespoonfuls or proportion provided by the Kenya Tissue and Transplant Authority).
* All consent documents must have a version number, date and be signed and stamped by the Head SERU.
* In this template:
	+ Where there are square brackets, edit as appropriate
	+ Bold statements are mandatory
	+ Text in red and italics provides instructions to the researchers and should not be included in final 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 the Principal Investigator (s) first followed by co-investigators of the study (In cases, where you have a long list of Co-Is, list PIs, CO-PIs and only those Co-Is who will have direct interaction with participants).*

**Study Location:** *Indicate where the study will be conducted*.

**Introduction**

[You are being asked to take part in a research study. The box below tells you important things you should consider before deciding to join the study. We will provide more detailed information below the box. Please ask questions about any of the information provided in this document about the study 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 to choose whether to participate or not. There are no penalties and you will not lose anything if you decide not to join 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 participation in the study will last [*expected duration*].
* **Procedures and Activities.** We will ask you to [*briefly highlight the key research activities/procedures*].
* **Risks.** Most studies may 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 participant 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 participant. If there are no alternatives, state that, “Participation is voluntary and the only alternative is not to participate.”].*
 |

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

1. **Description of the Research:**
	1. *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-related must be distinguished.*
	2. *If specific testing (e.g. HIV testing, HLA typing) will be done as part of the research, this must be explained in a simplified manner that the participant can understand.*
	3. *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.*
	4. *If randomization or sequential assignment is planned, this must be explained in detail, including the process, criteria, and the potential impact on the participant's experience.*
	5. *If blood will be drawn, the volume per visit and the total volume for the entire study participation (teaspoons and millilitre equivalents) must be indicated. 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.*
	6. *The frequency and duration of specific testing, as well as the duration of the entire study should be specified. This will give participants a clear understanding of the time commitment required.*
	7. *The study participants should be informed that any changes made to the study or should new information become available, they shall be informed. The participant should be informed that if; clinically relevant data arises as a result of their participation in the study, that information will be disclosed to them and under what conditions.*
	8. *If a questionnaire will be administered or an interview conducted, a description of the questionnaire/interview and, 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.*
	9. *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 of the tests. This information must also be reflected in the body of the research protocol*
	10. *A description must be provided if data will be abstracted from medical records or from other confidential sources.*
	11. *The study participants must be informed (and consented) 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 and, identify genetic make-up that 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.*

*If the research is not about genomics, this section may be omitted*.

1. **Storage of specimen, exportation of samples and further studies:** (*Provide details about the samples to be stored or exported. Provide information on the destination of the samples (including the country and the laboratory) and the nature of the studies that will be undertaken*)
2. *It should be explained clearly if future use of the research specimen/data beyond the current study is anticipated:*
3. *The participant should be informed if the specimen/information to be used for future research will be shared with other researchers without additional consent with identifiers OR*
4. *The participant should be informed if the specimen/information to be used for future research will be shared with other researchers without additional consent without identifiers OR*
5. *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*
6. *The participant should be informed that they can* ***decline*** *to have their specimen/information used or shared with other researchers for future research.*
7. *If the research data/samples are to be destroyed after the study is complete, participants must be informed of the plan.*
8. *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.*
9. *The participant should be informed if the sample/information may be used for commercial profit even if identifiers are removed and that the participant* ***will share*** *in the commercial profit.*
10. *The participant should be informed if the sample/information may be used for commercial profit even if identifiers are removed and that the participant* ***will not share*** *in the commercial profit*.
11. **Potential Harm, Injuries, Discomforts or Inconvenience, Risks:** (*Examples of research-related risks/harms are psychological harms, social harms, physical harm, legal harms, economic losses or side effects of treatment. Where applicable, state that the study will take some responsibility for treatment of any harm arising from the study; such as compensation or payment for treatment, guidance and counseling etc. State the plans to minimise risks/harms related to the study*)
	1. *If there is no known or known harm/risk to the study participants, this should be clearly stated.*
	2. *If there is known or anticipated risk, this must be explained*.
12. **Potential Benefits:** (*Benefits in research are those activities that are directly attributed to participation as opposed to those that one would be entitled to regardless of participation. Benefits could be to the participant, community where the study is being conducted, and to the society. Do not use language that may mislead potential participants about the hoped-for benefits*)
	1. *If study participants will not benefit or might benefit directly from the study, this should be stated and the potential benefits should be described.*
	2. *If the community in general or a patient with a similar condition stands to benefit from the results of the study, this should also be explained.*
13. **Alternative Procedures or Treatments:**
	1. *If there is no treatment alternative, the alternative to participation in the study is non-treatment and this should be explained.*
	2. *If there is a treatment alternative(s), the alternative(s) should be identified and described.*
	3. *Comparative risks and benefits: a comparison of the risks and benefits of the proposed treatment versus the alternatives should be clearly explained, if applicable.*
	4. *Patient's right to choose: a statement affirming the patient's right to make an informed decision, including declining treatment should be included where applicable.*
	5. *If the research is not about a treatment, this section may be omitted*.
14. **Confidentiality:**
	1. *No information that reveals the identity of any study participant should be released or published without consent.*
	2. *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.*
	3. *The plan for maintaining confidentiality of research records and materials must be clearly explained. Examples should be given such as password-protected data storage, use of participant unique identifiers (and not names), lockable cabinets etc*
15. **Participant Data Rights:[[1]](#footnote-1)**

We are committed to ensuring that your data is secure. We have implemented appropriate physical, technical, and administrative measures to safeguard your personal data against unauthorized access, disclosure, or misuse.

Your data (including personal identifiers) will be stored for [*insert duration*] and will be deleted or anonymized after this period unless there is a legitimate reason to retain it for a longer duration.

*Where applicable, add a statement that participants data will only be transferred to institutions that are compliant with the provisions of the Data Protection Act 2019 and the Regulations thereto as regulated by the Office of the Data Protection Commissioner (ODPC)*

Under the Data Protection Act, 2019, you have the following rights regarding your personal data:

1. Right to Access: You can request a copy of your personal data that we hold.
2. Right to Rectification: You can request that we correct any inaccuracies in your personal data.
3. Right to Erasure: You can request that we delete your personal data.
4. Right to Object: You can object to the processing of your data in certain circumstances.
5. Right to know how your data is being used
6. **Data Breach: (Exposure of data to unauthorized persons)**

You shall be notified immediately upon learning of any actual or suspected misappropriation or unauthorized access to, loss of control or availability over, or unauthorized disclosure or use of Personal Data (a “Data Breach”) with respect to its activities under this Study.

KEMRI shall promptly investigate each Data Breach that it becomes aware of or has reason to suspect may have occurred and, in the case of an actual Data Breach, shall provide reasonable levels of access and information to the Study participant in connection with any investigation that we may desire to conduct with respect to such Data Breach.

KEMRI shall identify any reasonable steps that should be implemented to limit, stop or otherwise remedy any actual or suspected Data Breach. Parties shall cooperate, as reasonably necessary in making notifications about a Data Breach to competent authorities and affected individuals in accordance with Applicable Laws.

In case of a suspected data breach, report to the KEMRI Data Protection Officer through the email provided in section 14 below.

In the event of unresolved data protection related issues, you may also escalate the issue by filing a complaint to the Office of Data Protection Commissioner at: [ODPC](https://www.odpc.go.ke/file-lodge-a-complaint/)

Email address: complaint@odpc.go.ke

Telephone No: 0796954269

1. **Withdrawal of consent:**

You may withdraw your consent at any time by contacting the research team. If the issue remains unresolved, you can reach out to SERU at [Telephone numbers: 020-2722541, 0717719477; Email address: seru@kemri.go.ke ]. However, please note that the withdrawal of consent will not affect the lawfulness (rightfulness) of processing based on consent before its withdrawal.

1. **Reimbursement:**
	1. *Study participants or their parents/guardians can be reimbursed for loss of wages, transportation expenses and for their time.*
	2. *There should be mechanisms for compensating participants in case of harms or injuries related to the study participation.*
	3. *It should be clearly stated that if the study participant withdraws from the research, that there will be appropriate pro-rated reimbursement, where applicable.*
	4. *A token of appreciation may be presented after completion of the study, but this should not be mentioned in the informed consent document but must have been indicated in the body of the study protocol.*
	5. *Include specific information whenever study participants will receive an inducement*.
2. **Participation:**
3. *If there are parts of the research study in which a study participant may choose not to participate, this should be clearly explained.*
4. *Parents/guardians of study participants should be made aware that assent may be required from their child. Note that children aged between 13-17 years provide assent in addition to parental consent.*
5. *All study participants must be given a copy of the signed and dated consent form to keep.*
6. *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*.
7. **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. Where applicable, include sponsor details*.

1. **Contact:**
	1. 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*.
	2. 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.go.ke
	3. In the event of any concern relating to your data rights, please contact Data Protection Officer at dataprotection@kemri.go.ke
2. **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*)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **S.No.** | **Statement** | **Yes** | **No** | **N/A** |
|  | **Consent for future research** | **Yes** | **No** | **N/A** |
|  | I agree for my specimen/information to be used for future research |  |  |  |
|  | I agree for my specimen/information to be used for future research with my additional consent |  |  |  |
|  | I agree for my specimen/information to be used for future research with my identifiers |  |  |  |
|  | **Consent for sharing**  | **Yes** | **No** | **N/A** |
|  | I agree for my specimen/information to be shared with other researchers |  |  |  |
|  | I agree for my specimen/information to be shared with other researchers with my additional consent |  |  |  |
|  | I agree for my specimen/information to be shared with other researchers with my identifiers |  |  |  |
|  | **Consent for shipment and storage of biological specimens** | **Yes** | **No** | **N/A** |
|  | I agree for my biological specimens to be shipped outside the country *(state where and to whom the specimen/information will be shared)* |  |  |  |
|  | I agree for my biological specimens to be stored outside the country  |  |  |  |
|  | **Consent for data transfer and storage**  | **Yes** | **No** | **N/A** |
|  | I agree for my data to be transferred out of the country for research purposes *(state where and to whom the data will be shared)* |  |  |  |
|  | I authorize the storage of data collected as a part of this study for use in future research studies. |  |  |  |
|  | **Consent for notification of research findings**  | **Yes** | **No** | **N/A** |
|  | I wish to be notified by researchers in the event of research findings of possible importance to my family members or myself.  |  |  |  |
|  | I agree that the researcher may use any appropriate identifier (*Telephone Number, National ID number, etc*.) to locate me in the future. |  |  |  |

*(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.)*

**SIGNATURE OF PARTICIPANT**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant Date

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­­­­­­­­­­­­­­**

**Permanent Physical Address of Participant**

***(****Use the following signature blocks for representative, parents, illiterate, disable 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 laws.)*

**SIGNATURE OF LEGALLY AUTHORIZED REPRESENTATIVE**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Legally Authorized Representative

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship to the Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Legally Authorized Representative Date

**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.)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Administering Individual

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Administering Individual Date

**THUMBPRINT SECTION FOR ILLITERATE OR DISABLED PARTICIPANTS**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Thumbprint of Study Participant and Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent and Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Witness and Date

1. The participant as per the Data Protection Act (No. 24 of 2019) is referred to as data subject. [↑](#footnote-ref-1)