PARTICIPANT ID: …………………………………

INFORMED CONSENT FORM

**Study Title:**

Give a clear and concise title of the research.

**Sponsor(s) of the study:**

List the names of the sponsors and collaborating partners if any.

**List of investigators:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Investigators** | **Institution of affiliation** | **Role** | **Contact** |
|  |  |  |  |
|  |  |  |  |

**Introduction**

Provide a concise background of the study and a brief explanation of the study rationale – why the study is important.

Explain the reason why the participant is being asked to participate in the study, state the approximate number of individuals participating in the study and where it will be conducted.

**Purpose of the study:**

Provide a brief description of the purpose or ***what the study aims to achieve***. Include a statement that this is a study rather than provision of clinical care.

**Procedures:**

Briefly describe the procedures explaining how the participant will be involved and what will be required of the participant. Include a **description of the experimental components of the study if any, such as testing a new intervention, new procedure etc.**

State **the estimated duration the research participant will be involved in the study.**

If a study involves sample collection, briefly state the sample type, quantity and how it will be managed at the end. Inform the participant that they will be asked to sign a separate consent form if they agree to allow any left-over samples to be stored for future use. A separate consent form will also be needed for genetic testing which will be performed on their sample *<<if applicable>>*. Inform them that they can still participate in this study if they refuse genetic testing on their samples or if they refuse to allow the researchers to store their samples for a long time.

Provide appropriate guidance on how the participant will return to the standard of care after completion of their study visits <<*if applicable*>>

**Voluntary Participation:**

State that participation is voluntary. State that the participant has a right to choose not to participate or withdraw from the study at any time without giving a reason and without any penalty or loss of benefits to which they are otherwise entitled. Any research results obtained prior to your withdrawal of consent may however be used and some data may have already been published.

Give circumstances under which they may be removed from the study without their consent.

**Alternatives to Participation**

Inform participants about what possible alternatives are available other than participating in the study e.g. alternative procedures or courses of treatment.

**Risks and Discomforts:**

Describe the foreseeable risks and discomforts the participant may experience while in this study *[physical, social, economic and psychological]*. Also explain how risks will be minimized.

Include a statement that in case the participant feels unwell, they should feel free to contact the study team on *[insert contact]* and that if the participant is referred to hospital for a research related injury/ illness, the cost of referral and management of the condition shall be paid by the study *<<if applicable>>*.

**Benefits:**

Describe the anticipated benefits to the research participants, benefits to research communities or to others that may be reasonably expected to result from the study. If no direct benefits to the research participants are expected, clearly state this.

**Confidentiality:**

Describe how the privacy and confidentiality of the study participants will be maintained during and after the study. Include how the data will be stored and for how long.

Describe who will have access to data of the research participants. Include a statement that relevant research oversight bodies e.g. the School of Biomedical Sciences Research Ethics Committee (SBSREC), Uganda National Council for Science and Technology (UNCST) may access the participant’s private information to ensure compliance with ethical and regulatory requirements.

**Costs**

Describe costs to be incurred by the participant as a result of his or her participation in the study.

**Compensation:**

You will receive *[insert amount or description]* as compensation for your time, effort and inconvenience or discomfort experienced during the study.

Include a statement that the participant shall be compensated for research related injury and what it will consist <<*if applicable*>>.

**Reimbursement:**

Describe how the out of pocket expenses incurred by the participant, as a result of their participation in the study will be met (such as transport costs, refreshments and meals).

**Questions about the study**

If you have any questions or need more information about this study, please feel free to contact *[insert name of the principal investigator or other* ***research team member able to communicate in a language(s) understandable to the research participants****]* at *[insert email address]* or *[insert mobile number]*.

**Questions about participant rights**

If you have questions about your rights as a research participant, you should contact the Chairperson of the School of Biomedical Sciences Research Ethics Committee (SBSREC),

Dr. Moses Ocan at email: biomedicalresearch62@gmail.com or 0782 355 302.

**Ethical approval:**

Include a statement that the study has been approved by the School of Biomedical Sciences Research Ethics Committee (SBSREC).

**Dissemination of findings**

State that research participants will get feedback on findings and progress of the study, personal study test results <<*if applicable*>> and that any new information that affects the study or data that has clinical relevance to research participants, including incidental findings, will be shared with willing participants and or their health care provider. State that findings will also be reported in summarized (aggregate) form in; publications, reports, presentations and dissemination workshops. No personally identifying information will appear in any report or publication.

**Incidental findings:** <<*if applicable*>>

Some unexpected but potentially important health-related information (incidental findings) may arise during the study.

Would you like to be informed if any such findings are discovered? Yes No

<<*Please tick one*>>

**Statement of consent:**

……………………………………………………. has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I understand that my participation in this study is voluntary and that I may refuse to participate or withdraw from the study at any time. I understand that refusal to participate or withdrawal after initial consent will not affect my current treatment and or future treatment <<*if applicable*>> I have had the opportunity to ask questions and all my questions have been answered satisfactorily. I am aware that in the use of the use of this information, my identity will be concealed. I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. I will receive a copy of this signed consent form.

Participant’s Name: ………………………………………

Participant’s Signature: …………………………………..

Make a thumbprint in the box below *<< if the participant can’t sign>>*

 Date: *[DD/MM/YYYY]*

**Person administering consent**

Name: …………………………………………………...

Signature: ……………………………………………….

Date: *[DD/MM/YYYY]*

*\*If the participant is unable to read and/or write, an impartial witness should be present during the informed consent discussion. After the written informed consent form is read and explained to the participant, and after they have orally consented to their participation in the study, and have either signed the consent form or provided their fingerprint, the witness should sign and personally date the consent form. By signing the consent form, the witness confirms that the information in the consent form and any other written information was accurately explained to, and apparently understood by the participant and that informed consent was freely given by the participant.*

Witness’ Name: …………………………………………………...

Witness’ signature: ………………………………………………...

Date: *[DD/MM/YYYY]*