PARTICIPANT ID: …………………………………

**PARENTAL 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 child is being asked to participate in the study, state the approximate number of children 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 <<*if applicable*>>.

**Procedures:**

Briefly describe the procedures explaining how the child will be involved and what will be required of the child. 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 child will be involved in the study.**

If a study involves sample collection, briefly state the sample type to be provided by the child, quantity and how it will be managed at the end. Inform the parent/ guardian that they will be asked to sign a separate consent form on behalf of the child 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 the child’s sample *<<if applicable>>*. Inform the parent/ guardian that the child can still participate in this study if they refuse genetic testing on the child’s samples or if they refuse to allow the researchers to store the child’s samples for a long time.

Provide appropriate guidance on how the child 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 parent/ guardian has a right to refuse the child from participating in the study. If they choose to allow the child to participate in the study, he/she has the right to withdraw the child from the study at any time or withdraw from the study at any time without giving a reason and without any penalty or loss of benefits to which they or the child 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 the child may be removed from the study without the parent’s or guardian’s consent.

**Alternatives to Participation**

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

**Risks and Discomforts:**

Describe the foreseeable risks and discomforts the child 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 child feels unwell, the parent/ guardian should feel free to contact the study team on *[insert contact]* and that if the child 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 child, benefits to research communities or to other children that may be reasonably expected to result from the study. On the contrary, if no direct benefits are expected to the children, include a statement clearly stating so.

**Confidentiality:**

Describe how the privacy and confidentiality of the child’s information will be maintained during and after the study. Include how the child’s data will be stored and for how long.

Describe who will have access to data of the children. 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 child’s private information to ensure compliance with ethical and regulatory requirements.

**Costs**

Describe costs to be incurred by the parent/ guardian and the child as a result of participating in this 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 compensation will be provided for any research related injury your child may suffer as a result of participation in this study and what it will consist <<*if applicable*>>.

**Reimbursement:**

Describe how the out of pocket expenses incurred by the parent/ guardian and the child, as a result of the child’s 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 child’s 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, the child’s personal study test results <<*if applicable*>> and that any new information that affects the study or data that has clinical relevance, including incidental findings, will be shared with you and or your child’s health care provider, if you wish. State that findings will also be reported in summarized (aggregate) form in; publications, reports, presentations and dissemination workshops. No personally identifying information about your child will appear in any report or publication.

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

Some unexpected but potentially important health-related information about your child (called incidental findings) may be discovered 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 as a parent/ guardian regarding this study. I understand that allowing my child to participate in this study is voluntary and that I may choose to withdraw my child from the study at any time without giving reason and without affecting my child’s current 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 the information about my child, my child’s identity will remain confidential. I understand that by signing this form, I do not waive any of my/ my child’s legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing for my child to participate. I will receive a copy of this signed consent form.

Parent’s/ Guardian’s Name: ………………………………………………

Parent’s/ Guardian’s Signature: …………………………………………..

Make a thumbprint in the box below << *if the parent/ guardian can’t sign*>>

 Date: *[DD/MM/YYYY]*

**Person administering consent**

Name: …………………………………………………...

Signature: ……………………………………………….

Date: *[DD/MM/YYYY]*

*\*If the parent/ guardian 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 parent/ guardian, and after they have orally consented to the child’s 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 parent/ guardian and that informed consent was freely given by the parent/ guardian.*

Witness’ Name: …………………………………………………...

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

Date: *[DD/MM/YYYY]*