**PARTICIPANT INFORMATION SHEET**

|  |  |  |  |
| --- | --- | --- | --- |
| Version |  | Date |  |

Study Title:

|  |  |  |  |
| --- | --- | --- | --- |
| SCC: |  | Protocol: |  |

Sponsor & Funder:

What is informed consent?

You are invited to let your child take part in a research study. Before you decide, you need to understand why the research study is being done and what it will involve. Please take time to read the following information or get the information explained to you in your language. Listen carefully and feel free to ask if there is anything that is not clear or you do not understand. You may also wish to consult your spouse, family members, friends or others before deciding to let your child take part in the study.

If you decide to allow your child to join the study, you will need to sign or put a thumbprint on a consent form saying you agree for your child to be in the study. You will receive a copy of this.

Why is this study being done?

The results of the study will be made available to your community.

What is the new vaccine/drug?

What does this study involve?

In case the investigator discovers your child is sick and decides that he/she cannot participate in the study because of that, he/she will receive immediate care at the study site and then be referred to the appropriate health facility.

If the research study needs to be stopped, you will be informed and your child will have the normal medical care.

What will happen to the samples taken in this study?

Please include if genetic testing will be done and if samples will be sent out of the Gambia

What harm or discomfort can you expect in the study?

What benefits can you expect in the study?

Will you be compensated for your child’s/ward’s participation in the study?

You will not get paid for participation of your child in the study, but you will get either transport by MRC or get the costs for the transport reimbursed.

Are there other products or treatment?

What happens if you refuse to participate in the study or change your mind later?

You are free to let your child participate or not in the study and you have the right to stop his/her participating at anytime without giving a reason. This will not affect the medical care that your child would normally receive.

In case you decide to withdraw your child’s participation during the study we will not work on your child’s samples without your permission, but any information already generated from the samples until the time of withdrawal will be used and samples already collected, for which you have given consent, will also be analysed and data used. The study doctor may also ask for tests for your child’s safety.

Should any new information become available during the study that may affect your child’s participation, you will be informed as soon as possible.

What compensation will be available if your child is injured during the study?

We will be responsible to provide for treatment caused by procedures of the research study through the MRC indemnity arrangement or insurance. If your child has an unwanted reaction, we will treat him/her or refer him/her as needed.

If medical treatment is required as an emergency, please refer to your health centre or clinic and contact the field worker who gave his/her telephone number to you or contact Dr [Name] on [Phone number].

How your child’s information will be kept and who will be allowed to see it?

All information that is collected about your child in the course of the study will be kept strictly confidential. Your child’s personal information will only be available to the study team members and might be seen by some rightful persons from the Ethics Committee, Government authorities and sponsor.

Who should you contact if you have questions?

If you have any queries or concerns you can contact Dr [Name] or Dr [Name] on [Phone number]and you can always call the personal numbers of the study staff given to you. If you have any concerns you can also contact staff at your health centre or clinic.

Please feel free to ask any question you might have about the research study.

## Who has reviewed this study?

This study has been reviewed and approved by a panel of scientists at the Medical Research Council and the Gambia Government/MRC Joint Ethics Committee, which consists of scientists and lay persons to protect your rights and wellbeing.

**Consent / Assent Form**

Participant’s Name

Participant’s Identification Number: |\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|

**OR**

(Printed name of parent) (Printed name of guardian)

I have read the written information **OR**

I have had the information explained to me by study personnel in a language that I understand

and I

* confirm that my choice to let my child participate is entirely voluntarily,
* confirm that I have had the opportunity to ask questions about this study and I am satisfied with the answers and explanations that have been provided,
* understand that I grant access to data about my child to authorised persons described in the information sheet,
* have received sufficient time to consider to let my child take part in this study
* agree to allow my child take part in this study.

*Tick as appropriate*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| I agree for my child’s samples to be shipped outside the Gambia.  I agree to further research on my child’s samples as described in the information sheet | | | | Yes  Yes | No  No | |
| Participant’s signature/ thumbprint\* for **assent**  (child aged 12-17 years) |  |  |  | | |  |
|  |  |  | Date (dd/mmm/yyyy) Time (24hr) | | | |
| Participant’s parent/guardian signature/thumbprint\* |  |  |  | | |  |
|  |  |  | Date (dd/mmm/yyyy) Time (24hr) | | | |
| Printed name of impartial witness\* |  | | | | | |
| Signature of impartial witness\* |  |  |  | | |  |
|  |  |  | Date (dd/mmm/yyyy) Time (24hr) | | | |
| Printed Name of Person obtaining consent |  | | | | | |
| **I attest that I have explained the study information accurately in** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **to, and was understood to the best of my knowledge by, the participant/parent/guardian and that he/she has freely given consent to participate *\**in the presence of the above named impartial witness (where applicable).** | | | | | | |
| Signature of Person obtaining consent |  |  |  | | | |
|  |  |  | Date (dd/mmm/yyyy) Time (24hr) | | | |

\**Only required if the participant is unable to read or write.*

A copy of this informed consent document has been provided for the participant.