**PARTICIPANT INFORMATION SHEET**

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

Study Title:

|  |  |
| --- | --- |
| SCC/Protocol No: |  |

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 study is being done and what will happen in it. Please take time to read the following information or get the information explained to you in your language. Listen carefully. You can ask questions if there is anything that is not clear, or you do not understand. You may also wish to speak to 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 the consent form.

Why is this study being done?

We will tell the results of this study to your community.

What is the new vaccine/drug?

What does this study involve?

If we find out that your child is sick and decide that he/she cannot join the study because of that, he/she will receive the care routinely available in The Gambia. Your child may be treated at the study site and if necessary, referred to a health facility that can manage the condition better.

If the research study needs to be stopped, we will tell you and your child will have the normal medical care if needed.

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 and your child will not get paid by the study, but MRC will provide transport or give you back the money for your transport.

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 join or not in the study and you are free to stop taking part at any time without giving a reason. You and your child will still get the normal medical care.

If you do not want your child to continue in the study, we will use only the samples and information already collected from your child.

The study doctor may ask to do some tests if needed for your child’s safety.

If we find any new information during the study that may change if your child can be in the study, we will inform you as soon as possible.

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

We will provide medical care if your child gets any problems from the study through the MRC indemnity arrangements *(this applies to MRC-sponsored research only)* or insurance.

If it is an emergency, please go to your nearest health centre or clinic and call immediately 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 study will be kept strictly confidential. Your child’s personal information will only be seen by the study team members, the sponsor and if necessary, the Ethics Committee and Government authorities.

Who should you contact if you have questions?

If you have any questions or are worried you can call Dr [Name] or Dr [Name] on [Phone number]and you can always also 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 hospital [Phone number].

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

## Who has reviewed this study?

The study has been checked by scientists at the Medical Research Council and by the Gambia Government/MRC Joint Ethics Committee. The Ethics Committee protects your rights and wellbeing and has given permission for it to take place.

**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 happy with the answers that have been provided,
* understand that I allow access to the information about my child by the persons described in the information sheet,
* had enough time to think about whether I want 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 including genetic testing | | | | Yes  Yes | No  No | |
| Participant’s signature/ thumbprint\* for **assent**  (child aged 12-17 years) |  |  |  | | |  |
|  |  |  | Date Time | | | |
| Participant’s parent/guardian signature/thumbprint\* |  |  |  | | |  |
|  |  |  | Date Time | | | |
| Printed name of impartial witness\* |  | | | | | |
| Signature of impartial witness\* |  |  |  | | |  |
|  |  |  | Date Time | | | |
| Printed Name of Person obtaining consent |  | | | | | |
| **I attest that I have explained the study information accurately in** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **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).** A copy of this ICF has been provided to the participant. | | | | | | |
| Signature of Person obtaining consent |  |  |  | | | |
|  |  |  | Date (dd/mmm/yyyy) Time (24hr) | | | |

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