**PARTICIPANT INFORMATION SHEET**

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

Study Title:

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

Sponsor & Funder:

## What is informed consent?

You are invited to take part in a research study. Participating in a research study is not the same as getting regular medical care. The purpose of normal medical care is to improve one’s health. The purpose of a research study is to gather information that may be useful in the future for the whole population. Your choice to participate or not will be respected. It is your decision and you can stop any time without giving any reason.

Before you decide you need to understand all about the study 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 you do not understand. Ask for it to be explained until you understand it. You may also wish to discuss with your husband/wife, family members or others before deciding to take part in the study.

If you decide to join the study, you will need to sign or thumbprint a consent form saying you agree 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 you are sick and cannot join the study, you will receive the care routinely available in The Gambia. You may be treated at the study site and if necessary, you will be referred to a health facility that can manage the condition better.

If the research study needs to be stopped for any reason, we will tell you and you will have normal medical care if you need it.

## 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 participating in the study?

You 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 join the study or not and you have the right to stop being in the study at any time without giving a reason. You will still get the normal medical care.

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

*Indicate if continued follow-up would be recommended for safety reasons even after withdrawal.*

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

## If you are injured in the study what compensation will be available?

We will provide medical care if you get any medical problems from the study through the MRC indemnity arrangements *(this applies to MRC-sponsored research only)* or insurance. If you have an unwanted reaction, we will treat you or refer you as needed.

If it is an emergency, please go to your nearest health centre or clinic and call immediately the research team or field worker who gave his/her telephone number to you or contact Dr [Name] on [Phone number].

## How will personal records remain confidential and who will have access to it?

All information that is collected about you in the study will be kept strictly confidential. Your 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 worried you can call [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 call 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?

This 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 Form

Participant Identification Number: |\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|

 (Printed name of participant)

[ ]  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 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 me by persons described in the information sheet,
* had received enough time to think about whether I want to take part in this study,
* agree to take part in this study.

*Tick as appropriate*

|  |  |
| --- | --- |
| I agree for my samples to be shipped outside of The Gambia  |  Yes **[ ]**  No **[ ]**  |
| I agree to further research on my samples including genetic testing | Yes **[ ]**  | No **[ ]**  |
| Participant’s signature/thumbprint\* |  |  |  |  |
|  |  |  | Date Time  |
|  |  |  |  |
| Printed name of impartial witness\* |  |
| Signature of impartial witness\* |  |  |  |  |
|  |  |  | Date Time  |
| Print 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 and that the participant 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 staff obtaining consent |  |  |  |
|  |  |  | Date (dd/mmm/yyyy) Time (24hr) |

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