

Study of severe undifferentiated febrile illness outbreaks in Sudan

PARTICIPANT INFORMATION SHEET (v 13.12.17)

I am working with the Federal Ministry of Health, the University of Karary and researchers from England to help find out what is causing the cases of severe feverish illness in this area. We would like to invite you/your child/ the patient you have brought in to take part in this study.

[For parents/guardians of a child]: We are asking you because you are the parent or guardian of a child who is too young to consent to taking part in research themselves. If your child is older than 12 year, we will also ask him/her in addition if they are willing to take part.

[For the representative of someone to ill to consent for themselves]: We are asking you because the person you have come with is not able to consent because he/she is too ill or does not have the capacity to do so. We would like to know if you think he/she would want to take part in the study.

Before you decide: it is important for you to understand why the research is being done and what it involves. I will explain this study to you. Please ask me if there is anything that is not clear, or if you would like more information or more time to decide. You/the patient are completely free to decide whether to take part or not. What you decide will not affect your/their care or treatment in any way. Please take time and think about this information carefully.

What is the study about?

We suspect a disease is affecting your community. We want to find out what is causing the illness to help the health authorities find better ways to prevent and treat the illness. To do this we need to know as much as possible about the illness and people who are affected.

What will happen if I take part in this study?

We will ask questions about the your/the patient's symptoms and about your/their life before they became ill. We will take a blood sample and a throat swab. These samples will be in addition to those needed for your treatment. If there is leftover sample after tests done by your doctors for treatment, we will store that to be tested. When you/the patient is discharged home, we will ask you to come back after 4 weeks if possible, so that we can take another blood test.

What will happen to the samples?

We will use the samples to find out what is causing the illness and to look at how your body fights the infection. We will also use the blood sample to look at factors in your/the patient's body find out what makes some people more susceptible to infection. Some of these tests may be done in another country.

We would like to store the samples taken and use them for future medical research. If we want to do further tests on these stored samples we will ask for permission first from the authorities who have given approval for the study.

Who will see the information that is collected?

Your name will be removed from the questionnaire before it is analysed. All data will be stored in a way that only authorised people can access it. You will not be identified in any published information. The

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information and samples will be labelled only with a number so that they cannot be linked to you/the patient. Only the people responsible for your/the patient's care and for this study will know that you/they were a part of the study. The information and samples we collect from you during this study may also be looked at by authorised public health officials who are responding to the illness and following up cases.

Are there any benefits to taking part in this study?

There is no benefit to you personally. The information we get from this study may not be available in time to affect your care. Any results that are available in time will be given to your doctor. The information we learn may help in caring for other patients in the future.

What are the risks of being in the study?

Being a part of this study means more samples may be taken than are needed for your normal care. Whenever possible these samples will be taken at the same time as the normal samples to reduce the extra procedures. There is a risk of pain or irritation when samples are taken. The tests we do to look at factors in the genes will be done on samples without participant names and individual results will not be given to participants.

Who is responsible for my care?

The Federal Ministry of Health medical and nursing staff working in the clinic or hospital are responsible for all care for your illness. You can ask these staff if you have any questions or concerns about your care. The research team is not involved in your care, but we will answer any question you have about the study or the sampling.

Can I request that I stop taking part in the study at any point?

Yes, you can stop taking part at any time without giving a reason and without affecting your care. Any samples that have not already been analysed can be destroyed if you request it.

What if I have any problems or would like further information about the study?

If you have any problems or would like further information at any time, you can contact:

The Study Field Work Supervisor on xx xxx xxxx, **ADD PHONE NUMBER.**

Or

The Principal Investigator on xx xxx xxxx **ADD PHONE NUMBER.**