

Lassa Virus Survivor Participant Information Sheet

My name is xxx and I am working with the UK Public Health Rapid Support Team and Kenema Government Hospital. We are carrying out a study to understand whether we can find immune responses to Lassa fever in oral fluids. The study has been approved by the Sierra Leone Ethics and Scientific Review Committee and the London School of Hygiene & Tropical Medicine Ethics Committee.

You/your child are being invited to take part in this research study. Before you decide to take part, it is important for you to understand why the research is being done and what it will involve. Please read this information about this study, or I can read it to you. Please ask me if there is anything that is not clear or if you would like more information.

WHAT ARE WE TRYING TO LEARN WITH THIS RESEARCH STUDY?

Lassa Fever can cause severe illness in adults and children. We know that many people who have had Lassa fever develop ‘antibodies’ - a protection in their body - that lasts a long time after they recover. Usually we measure this protection by taking blood, but we think it could be measured in the “oral fluid” found in the mouth and that this would be easier for patients, health-workers and researchers. We have developed a new method to test oral fluid and we are asking you to give an oral fluid and a blood sample so that we can test whether this new method can measure the Lassa Fever antibodies accurately and whether it is as good as, or better than, using blood. If we find this is true, we and other researchers would be able to ask for oral fluids samples instead of blood samples to better understand Lassa fever and Lassa virus transmission.

WHY ARE WE ASKING YOU TO PARTICIPATE?

We are asking people who have had Lassa Fever and who were treated at the Kenema Government Hospital to take part in the study. We think you may have the antibodies we are looking for in your blood and oral fluids.

WHAT HAPPENS IF I DON'T WANT TO PARTICIPATE IN THE STUDY?

You are free to refuse to participate in this study, or to withdraw at any time. Refusal to participate or withdrawal will not affect you/your child in any way.

WHAT WILL MY PARTICIPATION IN THIS STUDY INVOLVE?

If you choose to participate in this study, we will ask you for about one hour of your time. We will also ask you if you are happy for us to contact you again in future. If you agree to take part, we will first take your body temperature. If your temperature is 37.5°C or above, we will suggest that you visit the doctor as this may be a sign of an illness and we will not continue with the study.

If your temperature is 37.5°C or below, we will ask you to sign a form giving your consent to take part, or your consent for your child to take part. Then we will ask you some questions about who you are, about your general health, and about your exposure to things that cause Lassa fever. We will ask you/your child to give an oral fluid sample and we will take a 5ml blood sample. All samples will be analysed in Sierra Leone. We will also ask you for permission to look at the medical records from when you/your child were treated for Lassa fever at Kenema General Hospital so that we can see how the antibodies we measure are related to the illness.

IF YOU/YOUR CHILD ARE FOUND TO HAVE ANTIBODIES TO LASSA VIRUS WHAT DOES IT MEAN?

If your sample is positive, this relates to the Lassa fever or Lassa virus infection(s) you had in the past. It does not mean that you have Lassa fever or a Lassa virus infection now. It does not mean that you are infectious. However, because we cannot say that a positive test means you are immune (protected) against Lassa virus and you might still be able to get Lassa virus again, we will not tell you the result of the test as there is no benefit in knowing this.

WHAT HAPPENS TO THE BLOOD AND ORAL FLUID SAMPLES?

We would like to store your/your child's samples for possible later testing, for example if more accurate tests for Lassa Fever or other ways to investigate antibodies become available. If you do not want your samples to be stored, you can tell us and we will not store them, and if you change your mind in the future, you can tell us to destroy the stored samples. If we want to do further tests on the stored samples we will ask for permission first from the Sierra Leone Ethics & Scientific Review committee.

ARE THERE ANY RISKS INVOLVED WITH PARTICIPATING IN THIS STUDY?

There are no direct risks from participating in this study. There is a small risk of pain or irritation when samples are taken. Some of the questions we ask may remind you of painful events, such as when you were sick. If these questions are too difficult for you to answer, you are free to stop the interview at any time or leave the study completely.

ARE THERE ANY BENEFITS INVOLVED WITH PARTICIPATING IN THIS STUDY?

There will be no direct benefits from participating in this study, but you will be provided with a small amount of money for any inconvenience and transport costs.

WILL I BE ALLOWED TO WITHDRAW FROM THE STUDY IF I CHANGE MY MIND?

Taking part in this study is voluntary. You should join this study only if you want to and only if you are happy to give an oral fluid and blood sample. Even if you agree to give the samples, you can choose not to answer some or all of the questions. You can leave the study at any time and it will not affect you in any way. Not participating will not affect any health care that you might need in the future or your participation in any other research study.

WHO WILL SEE THE INFORMATION THAT IS COLLECTED?

Your name and other identifying information will be removed from the questionnaire before analysis, and all data will be stored in a way that only authorised people can access it. Your personal information will not be revealed in any published information.

We are happy to discuss any worries or queries. If you have any questions during the study or want any information, please contact:

The Study Coordinator on xx xxx xxxx, ADD PHONE NUMBER.

The Principal Investigator on xx xxx xxxx ADD PHONE NUMBER.

Thank you for your time and for considering this study.