



**MINISTRY OF HEALTH
AND SANITATION**
THE REPUBLIC OF SIERRA LEONE

MAIN STUDY
INFORMED CONSENT FORM FOR FOLLOW-UP VISITS
SUPPLEMENT

Updated 25 January 2016

You will be given a copy of the full Informed Consent Form.

Introduction

Thank you for participating in the Virus Persistence Study. At the beginning of the study, we explained all the procedures of the study and you signed an informed consent form. You also received a written copy of the informed consent form. There are a few additional things that we are planning to do to understand better the disease and that we wanted to inform you of and ask if you would be willing to participate in.

Please feel free to ask any questions to me, the main investigator (Dr. Deen from the Ministry of Health and Sanitation), or anyone else at any time so that you can feel comfortable making a decision to participate in this research study or not.

Type of Research Intervention

In addition to the testing of body fluids which has already taken place, we would also like to access your records from the laboratory and ETU clinic from the time you were treated for Ebola. Access to the information will permit to check the information we have from the questionnaires you have completed with the nurse, to ensure we have the right information. To sign the informed consent will imply that you grant us access to your records from the laboratory and ETU clinic from the time you were treated for Ebola

The tests for Ebola virus pieces that we performed are very reliable, however it may be possible that virus could still be present in the body but not able to be found in body fluids. There have been a very small number of survivors who became seriously ill after they recovered, and so we would like to ensure that you are well even after finishing the study and document health events that may have happened between your last negative results and the 3 and 6 months visit.

If you agree, we would like to invite you for a new visit at 3 and 6 months after your second negative sample. We will assess your health status by asking you questions about your health and will test your body fluids again at these time points. In case at least one of your body fluids tests positive at one of these two visits, then the same protocol as before when enrolled in the study will be observed, and we will follow you-up until you have two consecutive negative test results in a row for all body fluids. As before, the test results will be kept confidential.

Do you agree to have a 3 and 6 month visit? Yes No

The samples obtained will only be used for the here described Ebola testing, and will be safely and respectfully destroyed after this research is completed. The Ebola virus isolated in the laboratory may be saved and used for future scientific studies should you agree. The scientific use of any virus kept for additional studies, would be decided upon by the group of study responsible persons from the Ministry of

I have accurately read out the information sheet to the potential participant, confirm that the participant was given the opportunity to ask questions about the study, and all questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of this form has been provided to the participant.

Print name of Researcher:

Signature of Researcher:

Date:

DD/MM/YYYY