MINISTRY OF HEALTH
AND SANITATION
THE REPUBLIC OF SIERRA LEONE

PILOT 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 Pilot of 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. In the months that have passed since that time, 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 semen 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 semen. 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 semen again at these time points. Only semen samples will be collected. In case your semen 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 semen. As before, the semen 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 grown 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 Health and Sanitation, Sierra Leone, the WHO, US-CDC and Chinese-CDC.

You can decide if you allow for future study of the virus that might be produced from your samples or if you prefer that it is destroyed.

If you do not want the laboratory to keep any Ebola virus isolates that stem from your body fluids you may say so now, we will record it, and no virus will be stored.

Agree for laboratory to store virus: yes no
(Circle appropriate answer)

Who to Contact

You can always contact the main study investigator, Dr. Deen, Director of Clinical Studies at Connaught Hospital, Freetown – Tel: 076865597. In addition, each participant will be given the name and contact telephone number of the study physician for the sites of enrollment and follow-up.

This proposal has been reviewed and approved by an ethical review board linked to the Ministry of Health in Sierra Leone, which is a committee whose task it is to make sure that research participants are protected from harm. It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is funding/sponsoring/ and supporting the study.

Do you have any questions? Are you willing to participate in this research study?

Certificate of Consent

I have received the foregoing information, and it has been read to me. I have had the opportunity to ask questions about it and any questions that I have were answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant: _____

Signature/Thumbprint/Mark of Participant: _____

Date: _____
DD/MM/YYYY

If illiterate

Participants who are illiterate should include their thumb-print or mark, and a witness who is literate should also sign (if possible, this person should be selected by the participant).

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of Witness: _____

Signature of Witness: _____

Date: _____
DD/MM/YYYY

Statement by the researcher/person taking consent

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