Attachment 2 — Example Consent Form for Study Participants

[INSTITUTIONAL LETTERHEAD FROM SIERRA LEONE MOHS]

Consent form for participants in the study of Ebola virus in body fluids from survivors

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for your signature or mark if you agree to take part)**

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

PART I: Information Sheet

Introduction

Hello, I am a health care worker with the Ministry of Health and Sanitation (MoHS). The MoHS together with the World Health Organization (WHO) and the U.S. Centers for Disease Control and Prevention (CDC) are conducting a research study and we would like to talk to you about participating. We are looking for participants who are adults over the age of 18 years who have survived Ebola Virus Disease. Can I give you more information?

This goal of this research study is to investigate how long the virus can be found in different body fluids of survivors, other than blood. The main investigator for this research study is Dr. Deen from the Ministry of Health and Sanitation.

I would like to give you information about the research study and invite you to participate if you are eligible. It is your decision whether you want to participate or not. Please feel free to ask any questions of me, the main investigator, or anyone else at any time so that you can feel comfortable making a decision to participate in this research study or not.

Purpose of the research

We know that Ebola is a contagious disease that is most commonly passed from person to person by direct contact with body fluids like vomit, stool, or blood from a person who is sick with Ebola. In the Ebola Treatment Center, we check blood tests to make sure the virus is no longer present in the blood before a survivor is discharged to home. However, the Ebola virus may still be present in small amounts in other body fluids of survivors. For example, the Ebola virus has been found in male semen for up to 3 months after recovery. This research study will investigate how long the Ebola virus can be found in body fluids from survivors including semen (if you are a man), vaginal fluid (if you are a woman), breast milk (if you are a lactating woman) as well as urine, stool, sweat, and tears from all participants who agree to provide these samples.

If you are an Ebola survivor over the age of 18 years, your participation in this study is important for our research to understand of how long the Ebola virus can be found in body fluids other than blood.

Type of Research Intervention

We are inviting Ebola survivors to undergo testing for the Ebola virus on samples of their body fluids in order to learn how long it takes the virus to leave these different types of body fluids. We are not studying a new type of medicine or a new type of treatment as part of this research study and therefore the research does not involve risks that are not known in advance. However, the results of the presence of the virus in a survivor's body fluids may generate stigma and discrimination and this is addressed under the paragraph "Risk and benefit".

Participant selection

For this study, we invite adults at least 18 years old who have recovered from Ebola virus disease. Upon volunteering for this study we will ask you to present your Ebola discharge/survivors' certificate.

- ***Example of question to elucidate understanding:*** *Do you understand what the study is about?*

Voluntary Participation

Your participation in this research study is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, you can continue to receive all the same services offered by the MoHS for survivors, and nothing concerning your medical care will change. You may change your mind and stop participating at any time, even if you had agreed to participate earlier.

- ***Examples of question to elucidate understanding:*** *Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

Overview of Study Procedures

Study participants will be invited to attend several study visits at the study clinic. At each visit a trained counselor or nurse will ask a set of interview questions in a private setting. After the interview, we will request that you submit samples of certain body fluids depending on if you are a man or women or a lactating women (for example: semen, vaginal swab for vaginal secretions, urine, rectal swab for stool, sweat, tears or breast milk). These samples will be sent to the CDC laboratory in Sierra Leone and tested for the Ebola virus. If the sample tests positive for the Ebola virus, a portion of that sample (for example, part of the semen sample that was submitted) will be sent to the CDC in the United States for further testing. Each study visit will last about an hour, and visits will be about two weeks apart for all participants except for lactating women who will be asked to return every 3 days for follow-up visits. You will be given all of your Ebola test results and the results will be explained to you. When you have two negative tests in a row from all the body fluids tested, your participation in the study will end. You may decide to stop your visits at any time during the study. An optional HIV test and counseling will be offered to all participants. If you chose to be tested, the results will be kept confidential and will be shared with you. If you test HIV positive, your will be referred to HIV services provided by the MoHS.

Description of Participation

At the study visits, you will be asked a set of questions about the time you were sick with Ebola, some general questions about your health, as well as personal questions about your sexual behavior after you recovered from your illness and from the time of your last visit. The interviews will be done in private by a trained health care worker and all of your answers will be kept confidential. You can decline to answer certain questions if you do not feel comfortable or simply choose not to answer. If you decide not to answer certain questions you can still participate in the study.

In order to check whether the Ebola virus is still present in certain body fluids, we will test samples from your body that you agree to provide. Sample collection will be done in a private place and the samples will be collected by yourself after we give detailed instructions. For samples that are not intimate they will be taken in the presence of a trained health care worker, who can assist if needed.

For example, with your permission a trained health care worker may collect sweat from your armpit, saliva from your mouth, and tears from your eyes. The other specimens you can collect yourself in private. For the urine test we will ask you to pass urine into a special cup. For the rectal or stool test, we will give you a soft cotton swab to check your anus. The swabbing is usually not considered painful, but may feel uncomfortable. If you are a woman, we will give you another soft cotton swab to check your vagina yourself. For the semen collection, we will ask you to spend time alone in a private room to masturbate and provide semen in a special cup.

All of these samples will be sent to the CDC laboratory in Sierra Leone for initial testing for the Ebola virus and the test results will be offered to you. If the sample tests positive for the Ebola virus, a portion of that sample (for example, part of the semen sample that was submitted) will be sent to the CDC in the United States for further testing. This test will confirm if the Ebola virus found in your sample is viable (or is able to replicate and grow) and thus could possibly infect another person. It could take several months but the results can be shared with you.

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 Sierra Leone, the WHO and the CDC in each case. 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)

During your first visit we will also offer you the possibility to get tested for HIV if you would like. The test involves a skin prick where we take a few drops of blood for analyses. If you test positive a second test will be done to confirm your status. The answer to the test will be given to you in the same confidential setting by the same health care worker/counsellor that you

discuss with in relation to Ebola. You will get the answer to the HIV test the same day. Should your test be positive the counsellor/health worker will explain to you where to find further care and support, including treatment if needed.

Participation

Each study visit should last about an hour, but might be shorter or longer depending on your needs. It is possible that some people will need study visits every two weeks for several months, and other people will need only three study visits total.

At each visit you will be seen by the nurse in charge of the study and the laboratory technician who will help with specimen collection. When needed or if you have particular question the study physician will come and meet with you.

You will be asked to return for another study visit every 2 weeks (or for lactating women, every 3 days) until you have two negative tests in a row from all of your body fluids.

- ***Examples of question to elucidate understanding:*** *Do you have any other questions? Do you want me to go through the procedures again?*

Side Effects

This study does not provide any medication or experimental treatments that would cause side effects.

Risks and Benefits

Some people may feel embarrassed discussing private topics during the interview, but the trained male and female nurses and counselors will keep all information confidential. Specimen collection may be uncomfortable and might cause pain or local infection. If this occurs, a study physician will be available to see you. In the unlikely event that you need medical treatment, your will be referred to the nearest MoHS survivor clinic or medical facility, without any charge. Receiving results of Ebola testing might be stressful to you. There is also a risk of possible stigma or discrimination against you from others in your community.

Benefits of the study include the opportunity for you to receive the results of Ebola tests on your body fluids and counseling on the meaning of the test results as well as information on how to prevent transmitting the virus to other people. It is your choice whether or not to receive the test results. Either way, the results will help inform our understanding of the Ebola virus and best ways to prevent Ebola from spreading in the future.

Participants will receive a monetary compensation of 120,000 Leones at each study visit, as well as condoms, counseling, and linkages to health services as needed. The 120,000 Leones will include coverage of the cost of a meal and for transport (estimated to be 70,000 Leones). There wonreceive a monetary compensation of 120,000 Leones at each study visit, as well as cbe given by the nurse at the end of each visit and a receipt will be signed by the participant.

Incentives

Participants will receive a monetary incentive of 120,000 Leones at each study visit, as well as condoms, counseling, and linkages to survivor resources.

- ***Examples of question to elucidate understanding:*** *Can you tell me about the risks and benefits of participating in this study?*

Confidentiality

Your study participation will be confidential. That means that your interview responses and Ebola test results will not be linked to your name or other personally identifying information. You will receive a study ID card with a number to identify you. You can answer the questions freely and all answers and results will be kept strictly confidential. Only the researchers will know what your study ID number is and we will lock that information up with a lock and key. We will not be sharing the identity of those participating in the research.

- ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?*

Dissemination

The summary of this research will be shared with the scientific community in the form of scientific publications. In addition, the summary will be provided to the communities affected by the Ebola epidemic through educational campaigns provided by the MoHS. It is very important to provide the most accurate information about the Ebola virus and how long it may be found in body fluids of survivors in order to stop transmission of the virus.

Right to Refuse or Withdraw

You are not required to participate in this study and refusing or withdrawing will not affect you in any way, or your family or your access to clinic treatment. You will still have all the benefits that you would otherwise have in relation to needs of treatment at the clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient or member of the community.

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 [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, and telephone number.]). It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is funding/sponsoring/supporting the study.

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

PART II: 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: _____

Day/month/year

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: _____

Day/month/year

For those that decide to participate in this research study, all the specimen that have been taken will be safely and respectfully destroyed after this research is finished. You can decide if you allow scientists to keep any Ebola virus that might be produced from the samples you provide in a secure laboratory to study in the future.

☐ I allow scientists to keep any Ebola virus produced from my samples in a secure laboratory for future study

☐ I would prefer that the Ebola virus produced from my samples is destroyed after this study

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: _____

Day/month/year