

Informed consent form for Module B cases who are participating in Breast Milk/Sweat Module

Consent Script

Background/Purpose:

You are being asked to volunteer to take part in a project about Ebola Virus Disease (Ebola) in breast milk and sweat. This is a project for women who have survived Ebola and are still making any breast milk. Before you decide whether or not to take part in this project, we would like to explain the purpose of the project, the risks and benefits to you, and what we would like you to do.

Ebola can be spread from person to person in different ways, such as through direct contact with the body fluids of a person who is sick with Ebola. Different types of body fluids may contain Ebola, such as blood, sweat, saliva, tears, semen, and breast milk. We are trying to find out how long Ebola stays in breast milk, and also whether it is present in sweat and for how long. This will help us know what to tell women who survive Ebola and want to continue breastfeeding their children.

Procedures:

If you decide to take part in this project, we will ask you questions about your health, your baby's or children's health, and how you feed your baby/children. We will ask you to provide us with a small amount of breast milk and sweat specimens that will be tested for Ebola. We would like you to continue to come to the Ebola treatment unit (ETU) and give breast milk and sweat specimens every three days until your breast milk tests negative for Ebola two times in a row. We will give you your test results during the follow up visits. On follow up visits, you may also be asked questions about you and your baby's health and nutrition. If your breast milk tests positive for Ebola, a portion of the sample 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.

All of the test results will be offered to you, although some results may take a long time before they are complete. The biological specimens obtained will be used only for Ebola testing, and will be safely and respectfully destroyed after the research is completed. If live virus is present in a specimen, that virus may be stored securely at the CDC and may be studied in the future if you are in agreement. 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.

Risks:

There is little risk to you for taking part in this project. Some women may feel shy about giving breast milk and sweat specimens.

No medicine or treatment is given as part of this study and therefore the research does not involve unforeseeable risks. However the results on persistence of the virus in breast milk may generate anxiety for the participant which will be discussed in depth with the nurse counsellor at each visit.

Confidentiality:

We will make every effort to keep your information private and secure. Your information and specimens will be labelled with a code number only. Your name will not be used in anything written about this project.

Participation

Each study visit should last about an hour, but might be shorter or longer depending on your needs. It is possible that some participant will need study visits every 3 days for several weeks, and other people will need only few 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 3 days until you have two negative tests in a row from breast milk and sweat.

Voluntary participation:

It is up to you to decide whether or not to take part in this project. If you decide not to take part, it will not impact your medical care. You can skip any questions for any reason and you may quit any time without consequence.

Benefit:

Your breast milk and sweat specimens will be tested regularly for Ebola. You may find peace of mind knowing your breast milk and/or sweat specimens are free of Ebola. The findings from this project will be used to help give mothers and healthcare workers better advice about whether and when it is safe to breast feed.

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 include coverage of the cost of the meal and transport (estimated to be 70,000 Leones). There won't be any additional costs to be covered by the participant. The compensation will be given by the nurse at the end of each visit and a receipt will be signed by the participant.

Request for more information:

You may ask more questions about the project at any time. 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.

STATEMENT OF CONSENT FOR ENROLLMENT

Personal ID Number: _____

Please sign (or place a mark) in the space below once you have:

1. Had the informed consent form read and explained to you and had all your questions answered
2. Have been told what will happen during the project
3. Have been told the good and bad things that might happen to you from being in the project
4. and choose to join the project by your own choice

Participant's name [print]

Participant's signature

Date (DD/MM/YYYY)

Project staff's name [print]

Project staff's signature

Date (DD/MM/YYYY)

For those that decide to participate in this research study, 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

Participant states that she Can sign her name Cannot sign her name

Witness required only for a participant who cannot sign her name:

I have observed the participant, _____, make her mark above:
Participant's name [print]

Witness's name [print]

Witness's signature

Date