Attachment 8 — Counselling Script

Hello, my name is [*counselor’s name*]. Welcome [*patient’s name*] and thank you for coming in today. I am a counselor with the study of Ebola survivors. The purpose of this meeting is to follow up from your previous visit and offer you the results from the laboratory tests of your body fluids. All the information discussed will be kept confidential. If you have any questions during our meeting, please don’t hesitate to ask me. If you have questions later, you can contact [*counselor name and contact information*]. You can also contact the study leader [*PI name and contact information*].Before discussing the results of your recent laboratory tests with you, I would like to confirm three things:

1. What is your study ID number? *[Check study ID card]*
2. May we please confirm your identity? *[Check study ID photo and/or government photo ID card]*
3. When did you provide study specimens? *[Check availability of Ebola test results for this study ID number and these specimen collection date/s]*

Thank you for submitting body fluid specimens and participating in this study of Ebola survivors. It is possible that Ebola virus might continue to be in certain parts of your body for some time after you recover from Ebola virus disease. We used a laboratory test to look for Ebola virus in your body fluid. A positive test result means that Ebola virus was found in your body fluid, but the test cannot tell us whether the virus is still alive in your body or if it is capable of infecting anyone else. A negative test result means that the virus was not found in the specimen you submitted. In this study, we will continue to offer you Ebola tests every two weeks until there are two negative test results in a row for each type of body fluid. The test results are for your personal information only. Regardless of your test results, you should not have sex (vaginal, anal, or oral sex) for at least three months or 90 days after recovery. Because Ebola virus can live in breast milk even after recovery, it is best for a woman who has had Ebola virus disease not to breastfeed if there are other safe ways to feed the baby. Receiving your test results is optional and the choice is entirely up to you. Before I continue, I would like to confirm:

1. Would you like to receive results of the Ebola tests from your body fluid specimens? [If yes, continue with this script. If no, stop and thank the participant.]

Ebola test results are usually available within 2 weeks after providing a body fluid specimen, although sometimes it might take shorter or longer than 2 weeks. For your study ID number, Ebola test results are currently available for the following specimens you submitted: [*Mention all specimen type/s by date submitted for which any results are available*].

What was my result? *[Repeat for each specimen for which participant desires results.]*

***FOR NEGATIVE TEST RESULTS:***

The test result for your *[semen/vaginal fluid/urine/rectal swab/sweat/tears/breastmilk]* on *[date of specimen submission]* was negative for Ebola virus. A negative result means that Ebola virus was not found in that specimen of your [*semen/vaginal fluid/urine/rectal swab/sweat/tears/breastmilk*]. Although the virus is probably gone, it is possible that virus could still be present in very small amounts. In this study, we will continue to offer Ebola tests until there are two negative test results in a row for each type of body fluid. Therefore, even though your test result was negative, we continue to recommend that you should not have sex (vaginal, anal, or oral sex) for at least three months or 90 days after recovery from Ebola. Also, it is best for a woman who has had Ebola virus disease not to breastfeed if there are other safe ways to feed the baby.

What questions do you have about these test results? *[Use scripts below to answer questions asked.]*

***FOR POSITIVE TEST RESULTS:***

The test result for your *[semen/vaginal fluid/urine/rectal swab/sweat/tears/breastmilk]* on *[date of specimen submission]* was positive for Ebola virus. It could mean that the Ebola virus is already dead and leaving your body, or it could mean that Ebola virus is still alive in that part of your body. The test cannot tell the difference. Like all Ebola survivors, you should not have sex (vaginal, anal, or oral sex) for at least three months after recovery. Also, it is best for a woman who has had Ebola virus disease not to breastfeed if there are other safe ways to feed the baby. As part of this study, we would like to check your *[semen/vaginal fluid/urine/rectal swab/sweat/tears/breastmilk]* again today, and also invite you to return here to participate in another study visit in 2 weeks. We will continue to offer you all of your test results. What questions do you have about these test results? (use scripts below to answer questions asked)

Do I need to return here for more Ebola tests in the future?

In this study, we will continue to offer Ebola tests until there are two negative test results in a row for each type of body fluid. *[Check whether there are any body fluids that still need two negative specimens in a row.]* Today, we would like to check your *[semen/vaginal fluid/urine/rectal swab/sweat/tears/breastmilk]* again, and also invite you to return here to participate in another study visit in 2 weeks.

Why did I have a negative test result before, and now I have a positive test result?

It is possible that the specimen that you submitted before may have not found a very small amount of virus that was in your body. That is why we wanted to collect two specimens, in order to be sure that the virus had truly left the body. We will continue to collect specimens until there have been two negative test results.

Can I infect anyone else with Ebola?

People who recover from Ebola develop some immunity to Ebola infection and do not pose a serious risk for spreading the infection to others through casual contact. However, because Ebola virus occasionally lives in sexual fluids (male semen or female vaginal fluid) even after recovery, it is recommended that Ebola survivors should not have sex (vaginal, anal, or oral sex) for at least three months or 90 days after recovery. If abstinence is not possible, a condom should be used every time. Also, it is best for a woman who has had Ebola virus disease not to breastfeed if there are other safe ways to feed the baby. Test results from this study are for your personal information only, and you should not do anything differently because of these test results.

What test did you use?

For this study, laboratory scientists used a PCR test that looks for genetic material (RNA) from the Ebola virus. In blood specimens, the test is very sensitive, meaning that if viral RNA is present in blood, the test is almost always positive. Nobody knows for certain how well this test works on other body fluids, because very few people who recovered from Ebola have had the opportunity to be tested. Also, this test cannot tell the difference between Ebola virus that is still alive and Ebola virus that is already dead. In this study, we will continue to offer you Ebola tests every two weeks until there are two negative test results in a row for each type of body fluid.

Can I have sex now?

For all Ebola survivors, the recommendation from the Sierra Leone Ministry of Health, WHO, and CDC, is to avoid having sex (vaginal, anal, or oral sex) for three months, or 90 days, after recovery from Ebola virus disease. If abstinence is not possible, a condom should be used every time. You should not do anything differently because of your test results from this study.

Can I breastfeed a child safely now?

In most situations, breastfeeding is the best choice for feeding an infant. However, for lactating women with Ebola virus disease, decisions about how to feed infants or other children must be made by weighing the risk of transmitting the virus through breastfeeding against the risks of stopping breastfeeding. For women who have survived Ebola, the Sierra Leone Ministry of Health, WHO, and CDC recommend that if you have a safe replacement to breastfeeding, you should not breastfeed an infant after recovery. Please remember test results from this study are for your personal information only, and you should not do anything differently because of these test results.

Can I breastfeed a child safely in the future?

Nobody knows for sure when it is safe to resume breastfeeding after recovering from Ebola. Experts from UNICEF have recommended waiting at least 8 weeks. However, the Sierra Leone Ministry of Health, WHO, and CDC recommend that if you have a safe replacement to breastfeeding, you should not breastfeed an infant after recovery. However, it is safe to breastfeed again following future pregnancies.

How do I know when I am cured of Ebola?

A person with Ebola is considered “cured” when the virus has left your blood and you are feeling better. Although you have already recovered from Ebola virus disease, it is possible that Ebola virus will continue to be found in other fluids from your body for weeks or maybe even months. The test results from this study cannot tell the difference between virus that is still living and virus that is already dead and leaving your body. Because Ebola virus can occasionally live in sexual fluids even after recovery, it is recommended that Ebola survivors should not have sex (vaginal, anal, or oral sex) for at least three months or 90 days after recovery. If abstinence is not possible, a condom should be used every time. Also, it is best for a woman who has had Ebola virus disease not to breastfeed if there are other safe ways to feed the baby. Test results from this study are for your personal information only, and you should not do anything differently because of these test results.

I am currently experiencing [clinical symptom]. Is that because of my test results?

It is possible for patients who had Ebola to have certain symptoms, such as muscle aches, fatigue, hair loss, abdominal pain and eye problems. If you are having symptoms now and would like a medical evaluation, we can help you seek medical care in a health-care facility. Regardless of your test results, you should not have sex (vaginal, anal, or oral sex) for at least three months or 90 days after recovery Also, it is best for a woman who has had Ebola virus disease not to breastfeed if there are other safe ways to feed the baby.

Do I need any medicine or other treatments because of my test results?

No special treatment is required for Ebola survivors. If you are having symptoms now and would like a medical evaluation, we can help you seek medical care in a health-care facility. Test results from this study are for your personal information only. Regardless of your test results you should not have sex (vaginal, anal, or oral sex) for at least three months or 90 days after recovery. Also, it is best for a woman who has had Ebola virus disease not to breastfeed if there are other safe ways to feed the baby.

Did you do any other tests? Did you do anything else with my body fluid specimen?

With your permission, the specimens you provided were tested for Ebola. All specimens are saved to do additional Ebola tests later on.. You will not receive the results of any additional Ebola tests. After the specimens are finished being tested for Ebola, they will be safely and respectfully destroyed. No other kinds of tests will be conducted on your body fluid specimens that are unrelated to Ebola.

I have another kind of question. Who can I ask for more information?

If you have questions later about your test results, you can contact [*counselor name and contact information*]. You can also contact the study leader [*PI name and contact information*] at any time.

Thank you again for the very important role you are playing in this study.