**Protocol for a phase 3 trial to evaluate the effectiveness and safety of a heterologous, two-dose vaccine for Ebola virus disease in the Democratic Republic of the Congo**

## Appendix 3A

Immunogenicity Informed Consent Form for adults in English, Version 1.1 (10 Aug 2020)

**Evaluation of a heterologous, two-dose preventive Ebola vaccine for effectiveness and safety in the Democratic Republic of the Congo**

**"The TUJIOKOWE Study" Immunogenicity Subset**
**Information Sheet and Informed Consent Form**

**LSHTM Protocol:** DRC-EB-001

**Principal Investigator (PI):**
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**Sponsor:** London School of Hygiene & Tropical Medicine, United Kingdom

**Site:** Democratic Republic of the Congo

## INTRODUCTION

The 'TUJIOKOWE study' is a research study to find out if a new two-dose vaccine called the 'Janssen Ebola vaccine' can protect people from getting Ebola and to check whether the vaccine is safe. The TUJIOKOWE study is being implemented by the Ministry of Health of DRC through the Institut National de Recherche Biomédicale (INRB), Epicentre, and the London School of Hygiene & Tropical Medicine.

When we started the TUJIOKOWE study, we planned to give everybody the second dose of the Ebola vaccine about two months after the first dose. Some people will now receive the second dose of Ebola vaccine later than originally planned. This is because it was necessary to temporarily close the study clinics due to the COVID-19 outbreak. We want to understand if people who receive their second dose of vaccine later than two months have the same immune responses as the people who received their second dose of vaccine at two months after the first dose. To do this, we will need to collect blood samples from approximately 50 adults, 25 adolescents, and 25 children participating in the TUJIOKOWE study who received the second dose of the Ebola vaccine after July 2020. We are asking you to join this small study (which we are calling the Immunogenicity Subset) and to provide two blood samples because you will be receiving the second dose of the vaccine after July 2020. If you agree to participate, one blood sample will be collected from you before the second dose of Ebola vaccine is given and the second blood sample will be collected 21 days later.

We would like to be sure that your body responds to the vaccine as well as people who received the second dose of the vaccine two months after the first dose. To check this, we will be looking at the antibodies that your body produces after you receive a vaccine. Antibodies are produced by your body after vaccination to protect you from infection. The information from testing your blood for antibodies will be very important when the vaccine is used to protect against Ebola in the future because it may not always be possible to give the second dose at exactly two months after the first dose of the vaccine.

If you are the parent or guardian of a child under 18 years of age and you agree to your child providing blood samples, you will need to sign separate documents for you and your child. If your child is aged 12 to 17 years old, he/she will also need to agree to provide blood samples himself/herself and sign a different document, called the immunogenicity assent form.

## DO I HAVE TO GIVE BLOOD SAMPLES?

You do not have to provide any blood samples. If you agree to provide blood samples, we will ask you to sign this consent form. If you do not want to give any blood samples, this will not affect your participation in the TUJIOKOWE study.

## WHAT WILL HAPPEN IF I AGREE TO GIVE BLOOD SAMPLES?

We will describe the blood collection process and answer any questions that you may have. If you would like a copy of the written information, we will give it to you. You will be asked to sign or put your fingerprint on this consent form. Putting your name or your fingerprint on the consent form means that you agree to provide blood samples, but you can change your mind at any time.

After you have given your first blood sample, you will follow the normal TUJIOKOWE study procedures to receive the second dose of vaccine. To have your second blood sample taken you will need to come to the study clinic for an extra visit 21 days after you have received the second dose of vaccine. If you participate in the Immunogenicity Subset, then we will give you some refreshments at the clinic.

## WHAT DOES GIVING BLOOD INVOLVE?

A small amount of your blood will be collected from you using a small clean needle. We will take blood before you get the second injection of vaccine and at 21 days after the second injection. To have your second blood sample taken, you will need to come to the study clinic for an extra visit 21 days after you have received the second dose of vaccine. For adults, we will collect approximately 5 mL (about 1 teaspoon) of blood each time you provide a blood sample.

As explained earlier, the blood samples you give will be used to test whether your body has produced antibodies in your blood against Ebola after vaccination. You will not receive the results of these tests because they are only for scientific research.

After we do our tests on your blood samples for the Immunogenicity Subset of the TUJIOKOWE study, we will destroy any remaining blood that has been collected from you. We will not use your blood for any other purpose except the antibody tests that we have explained in this consent form. Your blood samples will not be sold.

Your blood samples will be labelled with a code and not your name. Other information, such as sex, age, or health history might also be shared with other investigators, but your name will not be shared.

**WHAT ARE THE POSSIBLE RISKS OF GIVING A BLOOD SAMPLE?**

Providing a blood sample is generally safe but occasionally people experience pain, bruising, bleeding, or (very rarely) infection from giving a blood sample. The medical team will provide care if you experience side-effects from the blood sampling. They are available if you have any problems or questions.

**WHAT ARE THE BENEFITS OF GIVING A BLOOD SAMPLE?**

There is no direct benefit to you for providing blood samples in the Immunogenicity Subset of the TUJIOKOWE study. Your agreement to provide blood samples will help in the development of vaccines to prevent Ebola and, in the future, may help people in different parts of the world.

**WHAT HAPPENS TO THE BLOOD SAMPLES COLLECTED FROM ME?**

The blood samples collected from you during the Immunogenicity Subset of the TUJIOKOWE study, will only be used to understand how the Ebola vaccine works when the second dose is given more than two months after the first dose.

The samples will be coded in a way that only limited study staff can link them to you. Your blood samples will be tested in a laboratory in the United States. If any blood remains in DRC, it will be stored in the INRB laboratory in Goma. We will destroy all the samples in the United States and in Goma at the end of the study.

**WHO CAN I TALK TO ABOUT GIVING BLOOD SAMPLES?**

If you want to talk to someone about giving a blood sample or if you think you have been harmed by providing a blood sample, you can contact the following people:

1) The Principal Investigator responsible for this study

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|---|
| Professor Jean Jacques Muyembe<br>*Director General,* Institut National de Recherche Biomédicale, Kinshasa, DRC<br>Phone: 0898 949 289<br>Email: jjmuyembet@gmail.com<br><br>Local study representative<br>Dr Hugo Kavunga<br>Phone: 0823 875 153<br>Email: hugokavunga@gmail.com |

2) The DRC ethics committees that approved this study

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|---|
| Professeur Félicien Munday<br>National Ethics Committee<br>Kinshasa-Gombe, DRC<br>Phone: 0998 419 816<br>Email: feli1munday@yahoo.fr |
| Professeur Willy Bongopasi<br>Comité d'éthique de l'école de santé publique<br>Université de Kinshasa<br>Phone: 0999 952 341<br>Email: bongopasi@gmail.com |

If you have any questions about providing blood samples for the Immunogenicity Subset of the TUJIOKOWE study or about your rights, you may ask anyone on the study team at any time.

**PARTICIPANT IMMUNOGENICITY SUBSET CONSENT FORM**

**Title: Immunogenicity Subset of the TUJIOKOWE Study**

**Principal Investigator of this study: Prof. JJ Muyembe**

| **Statements** | **Please sign or fingerprint each box** |
|---|---|
| I have read the information in this form about giving a blood sample at two visits for the Immunogenicity Subset of the TUJIOKOWE Study (or I have had this information explained to me by the study staff in a language that I understand). The purpose of providing blood samples and the procedures to give blood samples have been fully explained to me. I was able to ask questions and have all of these questions answered to my satisfaction. | |
| I understand that my participation is voluntary, that I can withdraw consent to provide blood samples at any time without giving any reason, and that this will not affect my participation in the TUJIOKOWE Study. | |

**I am aged 18 years or older and I agree to provide Immunogenicity Subset blood samples during my participation in the TUJIOKOWE study.** (Please sign or put your fingerprint below)

| | | |
|---|---|---|
| | | ____/____/_____<br>*dd mon yyyy* |
| Printed name of adult participant | Signature/fingerprint of adult participant | Date |

| | | |
|---|---|---|
| | | ____/____/_____<br>*dd mon yyyy* |
| Printed name of investigator | Signature of investigator | Date |

*Complete this section if the participant is illiterate:*

**Witness to Consent Interview**

I witnessed the consent interview for the Immunogenicity Subset of the TUJIOKOWE Study in this document. I attest that I have explained the study information accurately to the participant or parent/guardian and was understood to the best of my knowledge by the participant and that he/she has freely given their consent to participate in my presence.

| | | |
|---|---|---|
| | | ____/____/_____<br>*dd mon yyyy* |
| Printed name of impartial witness | Signature of impartial witness | Date |

Attach ID barcode label below: