ADOLESCENT INFORMED ASSENT FORM
PARTICIPANT INFORMATION SHEET
This Informed Assent form is for children 12 - 17 years of age

TITLE:	**A Multi-Centre, Randomized, Double Blind, Phase 2b Trial to Evaluate the Safety and Immunogenicity of Janssen Ad26COVS1 (or mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccines and Novavax NVX-CoV2373 COVID-19 vaccines for Homologous and Heterologous Boosting in Adolescents and Adults Aged 12 to 64 Years with and without HIV infection in 3 African Countries (Kenya, Democratic Republic of Congo, and Rwanda).**
PROTOCOL NO.:	VIBRI COVID-19-001/2021 Protocol v3.0, Date 16 Jan 2023
SPONSOR:	Victoria Biomedical Research Institute (VIBRI), Kenya
PRINCIPAL INVESTIGATOR:	Dr. Lucas Otieno Tina, MD MPH
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Before you decide if you want to be in this study, it's important for you to understand why we're doing the research and what's involved. So please read this form carefully. You can discuss it with your parents or anyone else. There may be some words that you don't understand, or things that you want explained in more detail, because you are interested or concerned. Please ask me to stop at any time and I will explain them to you.

This form has two parts:

- An information sheet that provides information on the study.
- Assent statement (this is where you sign if you agree to participate).

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

Table 1:

Key Information for You to Consider
The study doctor is responsible for carrying out the study. • You can make a decision whether to take part or not. • You can say 'No' at any point of time. Even If you said 'Yes', you can always change your mind and say 'No' later. • If you want to be in the study but your parents/legally acceptable representative / caregiver refuse, you cannot participate. • We would still take good care of you no matter what you decide. • Our scientific question is: Does the vaccine produce a good immune response to protect people with or without HIV from getting COVID-19 illness? • If you join, your participation in this study will last for about 12 months. • If you join, you will have injections, blood draws, urine samples, and swabs of your nose. • The study will be looking at the Janssen COVID-19 vaccine and the Novavax COVID-19 vaccine for adults or NVX-CoV2373 vs mRNA (Moderna mRNA-1273 or Pfizer/BNT) COVID-19 vaccine for adolescents when given in a mix and match schedule as booster doses some months after you have had your first (or second dose) of a Covid-19 vaccine provided by the country's national vaccination program. • The study will enroll adolescents 12 to 17 years old and adults 18 to 64 years old. • Here are some risks of taking part: ❖ The most common risks are symptoms like fever, muscle aches and headaches after getting the study vaccine. ❖ There are other, less serious risks. We will tell you more about them later in this consent form. • We do not know if getting the study vaccine will benefit you in any way. • Take your time to decide. You may take an unsigned copy of this form home to reread and discuss with your family, friends and healthcare provider or doctor. • You may ask the study doctor and the site staff any questions • You can keep a copy of this form for your record.

Purpose of the Research:
Vaccine research is when a study team like us wants to collect information from people to find out if a vaccine can prevent people from getting ill. This document will tell you about a research project and the choice is up to you to take part in it or not.

Covid-19 is a very bad disease that is caused by a novel virus. Your body needs "antibodies" to fight against the disease. They are produced in the body when people get vaccinated against that disease.

This study is therefore being done to test the new Janssen COVID-19 vaccine and the Novavax COVID-19 vaccine in both HIV positive and negative for adults and Novavax COVID-19 vaccine and mRNA (Moderna mRNA-1273 or Pfizer/BNT) COVID-19 vaccine for adolescents. Doctors and scientists hope it will prevent or lessen the severity of COVID-19 disease.

The main purposes of this study are to investigate:

- If the Janssen COVID-19 vaccine and Novavax COVID-19 vaccine or adults or Novavax vs mRNA (Moderna mRNA-1273 or Pfizer/BNT) COVID-19 vaccine for adolescents boosts an immune response that protects against COVID-19 disease
- If the Janssen COVID-19 vaccine and Novavax COVID-19 vaccine or adults or Novavax vs mRNA (Moderna mRNA-1273 or Pfizer/BNT) COVID-19 vaccine for adolescents is safe
- To learn more about the side effects caused by the Janssen COVID-19 vaccine and Novavax COVID-19 vaccine or adults or Novavax vs mRNA (Moderna mRNA-1273 or Pfizer/BNT) COVID-19 vaccine for adolescents
- If the Janssen COVID-19 vaccine and Novavax COVID-19 vaccine or adults or Novavax vs mRNA (Moderna mRNA-1273 or Pfizer/BNT) COVID-19 vaccine for adolescents helps to prevent or lessen the severity of COVID-19 disease

You are invited to take part in this vaccine study.

1. Description of the Research:

In total, 1,950 participants including 300 adolescents will take part in this study across three study sites in Kenya, Rwanda and the Democratic Republic of Congo.

We are doing this study to find out more about these vaccines in children when given as booster doses, to see if they are well tolerated by your body and if they protect against Covid-19 disease.

Participation is voluntary? Do I have to do this?
You don't have to take part in this research if you don't want to. It's up to you. If you decide that you don't want to participate in the research, it's okay. Nothing will change. And even if you say "yes" now, you can change your mind later, and that will also be okay.

What will happen if you are in the study?
If you agree to be in the study and your parents give permission, we will ask you to:
Sign your name on this Assent Form and you will receive a copy.
When you are confirmed by the study doctor for you to join the study, it will take about 12 months for you to be in the study and you will be asked to come to the study site up to 7 times during this period.
We will ask questions about your health, illness and medication used.
We will look at your medical history to learn more about your health history.
The study will be carried out in two stages: in Stage 1, the booster vaccines will be given to adult participants 18-64 years. In Stage 2, the booster vaccines will be given to adolescents 12-17 years old and enrolment will begin after enrollment of adult participants. This will give more time for more adolescents to receive MoH primary vaccinations which only began recently. It will also provide an opportunity for including use of other COVID-19 vaccine platforms following availability of safety data.

We will do a physical examination before your vaccination, including body weight, body height and body temperature.
If you are a female, you will need a urine pregnancy test. If pregnant, you will not participate in this study. If you at risk of becoming pregnant, you must use a reliable birth control method during the study.
Birth control methods that can be used while in this study include:

a. Condoms (male or female)
b. Diaphragm with spermicide
c. Cervical cap with spermicide
d. Intrauterine device
e. Oral or patch contraceptives
f. Hormonal Contraceptives implants or injection e.g., Norplant®, Depo-Provera®.
g. Abstinence, as a form of contraception, is acceptable if in line with the participant's lifestyle.

NOTE: Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception. These procedures and laboratory test results must be confirmed by physical examination, by participant recall of specific date and hospital/facility of procedure, or by medical documentation of said procedure.

Tell your study doctor right away if you get pregnant during this period. If you get pregnant, the study doctor will want to follow up with you on the outcome of the pregnancy and collect information on the baby.

Booster Vaccination:
You may receive either a booster dose of Janssen (COVID-19) vaccine at day 0 or a booster dose of Novavax (COVID-19) vaccine at day 0 for adults or booster dose of Novavax (COVID-19) vaccine at day 0 or booster dose of mRNA (Moderna mRNA-1273 or Pfizer/BNT) COVID-19 vaccine day 0 for adolescents.

The study vaccine is given by injection. The needle is put into the muscle in your upper arm. When possible, the injection will be given in the arm you use less. The injection which will be given to you can hurt. Sometimes there can be bruising of the skin or your arm may be sore.
You will remain at the study site for observation for at least 30 minutes after receiving the vaccine and will also have a study paper diary given to you to fill every day for the next 7 days at home. Please record all medical events in the diary card after booster dose, including symptoms of side effects, medical history, medication, and other vaccine use. You will bring the completed study diary to the study clinic during your next visit.

In addition, if you become ill or injured as a direct result of the vaccine, you will receive appropriate care as provided by clinical trials insurance policy.
Please contact us at all times if any severe disease or symptom has occurred.

Samples: Table 2:

Procedure	**What is it?**	**When is it done?**
Blood draw/tests	The study doctor or staff will draw blood from a vein in your arm. You may have pain, get a bruise or irritation at the place where the needle goes into your skin. Some participants may faint. In rare cases, the blood draw can cause an infection. Across the 3 sites in Kenya, Rwanda and the Democratic Republic of Congo, the total amount of blood that will be drawn for purposes of the study during the entire follow up is 119 mL (about 12 Tablespoons). Out of this, the total amount of blood that will be drawn from participants to test the Body's Immune Responses will be 105mL (about 10 Tablespoons) for the majority of study participants. Should you become sick for any reason such COVID-19 disease, Malaria or other illnesses, the doctor or health provider may ask for additional blood draws for your medical assessment and treatment. You may be asked to repeat a blood test if there are safety or technical issues with the initial draw. Your blood will be used to check	All participants will have blood drawn at Visits: 1, 2, 4, 5, 6, and 7. Participants will have blood drawn at screening for health assessment including HIV, Blood Picture, Liver and Kidney function test. Participants will then have blood drawn to assess the body's immune response before and after vaccinations. Additional amount will be drawn from participants who develop COVID-19 disease. Sometimes you may need to repeat a blood test.

	• For confirmation of COVID-19 infection • Your immune response to the study vaccine • Assessment of your health and safety during the study Positive COVID-19 tests will be reported to applicable health authorities	
Urine sample	If you are a female who is at risk of getting pregnant, we will collect a urine sample from you to check for pregnancy.	Visit 1 and Visit 2

Looking for any Covid-19 illness:
When you enroll into the study, your parents/LAR will be asked to provide the name of your regular doctor and the hospital you would likely seek care at if you become seriously ill. This is so we can be sure to follow you to check your health. You and your parents/LAR should contact the study staff as soon as you start experiencing COVID-19-like symptoms. Study staff will monitor your health and may visit you in your home. If you seek health care for COVID-19 by a nurse or doctor at a clinic, or hospital, we ask that you and your parent/LAR inform the study staff about this and also the medical staff at the clinic or hospital. If you turn out to be positive for COVID-19, local Ministry of Health guidelines will require the study staff to inform the local health authorities to initiate the contact tracing system.

***Criteria/Symptoms of Suspected COVID-19 which trigger to proceed with collection of nasal or throat swab:**

Fever/Chills	New loss of taste or smell	Loose watery stools	Tiredness
Cough	Sore throat	Nausea or vomiting	Headache
Blocked nose or runny nose	Shortness of breath	Stomachache	Muscle pain

2. Is the vaccine considered to be safe?

The study vaccines in the context of this study are being used in an experiment to get additional information about the safety, immune response and how the vaccines work. Like most other vaccines, possible side effects include: itching, arm discomfort, pain and swelling at the site of injection, fever, chills, rash, muscle pains, joint pains, nausea and vomiting.

If you become sick during the research, we will look after you. The company responsible for the research has taken out insurance to reimburse your parents if you get sick because of taking part in the research.

3. What will you get from this participation?

You may receive no direct benefit but you will get the benefit of doctor's examination on a regular basis and the doctor will share the results. Findings of medical concern will be referred for proper care and treatment.

4. Confidentiality: Who is able to access my personal information?

We will not tell other people that you are in this research and we will not share information about you with anyone who does not work in the research study. After the research is over, you and your parents will be told which of the two injections you received and the results.
Information about you that was collected during the research will be kept somewhere safe and no-one but the researchers will be able to see it. Any information about you will have a number on it, instead of your name. Only the researchers will know what your number is, and we will secure that information under lock and key. It will not be shared with, or given to anyone, except people authorized to do so.

When we are finished with the research, and the results are available it will be shared with you and your parents. The research will be shared more broadly with people who are interested in this work.

5. Reimbursement:

You and your parents/LAR will receive compensation for your time and inconvenience during scheduled study clinic visits and reimbursement for transport based on the distance travelled and the local rates at each site. Payments may also be made for transport reimbursement during unscheduled study clinic visits. You and your parent or guardian will receive Ksh 1000 for inconvenience and time and about 500 Kenya Shillings as transport reimbursement depending on the local transport costs which will total to about Ksh 1500 per planned visit to reimburse you for such expenses. For unscheduled visits, you and your parent or guardian will receive Ksh. 300 as transport reimbursement. If your study-related costs exceed the specified amount and your parent or guardian has proof of such expenses, they will discuss with your study doctor.

6. Is there anything else?

Take your time to make your decision. If you want to participate in this research after we talk, please answer the following questions and write your name in the section below. We will write our name too. This shows we talked about the research and you want to take part in.
If you decide to participate and your parent agree, we'll give you a copy of this form to keep.

7. Who can I talk to?

You can ask any questions that you have about the study anytime including study related injury. If you have a question later that you did not think of now, you can call for any questions related to the study to the Study doctor or Amref ESRC on the numbers below:

	Study Doctor	ESRC
Name:	Dr. Lucas Tina	Amref ESRC
Telephone no:	+254 788 065080	+254795746777

8. Consent and signature:

If you still want to take part in the research, sign and date the Assent Form.

If you do not want to take part in the research, DO NOT SIGN your name.

Assent statement

- My mother, father, or person taking care of me knows about this study and they want me to be in it if I want to.
- I want to be in the study, but I know I can stop whenever I like.
- This study has been explained to me.
- I and my mother, father or person taking care of me can ask the study doctor any questions at any time.
- I will get a copy of this form.

PARTICIPANT

Printed name of participant (personally completed by participant) *:	
Date (personally completed by participant) *:	**DD / MMM / YYYY**
Signature of participant: *or thumb/finger print of the participant in case participant is illiterate*	

** To be completed by the witness in case participant is illiterate*

PERSON CONDUCTING CONSENT

Printed name of the Person conducting consent	
Date Person conducting consent:	DD / MMM / YYYY
Signature Person conducting consent:	

IMPARTIAL WITNESS (if applicable)

(*Witness signature is required in instances where the participant or caregiver is illiterate. Verbal consent must be obtained from the participant, in the presence of an independent and impartial witness who is present during the entire informed consent discussion. The witness's name, signature and date must be completed by the witness at the same time when consent is obtained from the participant and the document is signed and dated by the investigator. A competent witness for research purposes is a person who is 18 years or older, and of sound mind and who is not involved with the trial in any way)*

I hereby verify that verbal consent was obtained from the above participant and all sections of the consent was accurately explained to, and apparently understood by, the participant or the participant's legally acceptable representative. The participant has also been informed about the risks and the benefits of the research, understands such risks and benefits and is able to give consent to participate, without coercion, undue influence or inappropriate incentive.

Printed name of witness (personally completed by witness):	
Date (personally completed by witness):	DD / MMM / YYYY
Signature of witness:	