INFORMED CONSENT FORM
To be administered to parents/guardian and adults aged 18-64 years

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 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, Kenya
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You or your child are invited to take part in this research study.

Here are a few things for you or your child to know:

- Joining this research study is voluntary. It is your choice to participate or not.
- Joining this study is not part of your regular health care.
- Our scientific question is: Does the study vaccine produce a good immune response to protect people with or without HIV from getting COVID-19 illness?
- If you or your child join, your participation in this study will last for about 12 for children and 15-18 months for adults.
- If you or your child join, you or your child 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 Novavax vs mRNA (Moderna mRNA-1273 or Pfizer/BNT) COVID-19 vaccine for adolescents when given in a mix and match schedule as booster doses.
- The study will enrol 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 or your child more about them later in this consent form.
- We do not know if getting the study booster vaccine as a study participant will benefit you or your child in any way.
- Take your time to decide. You or your child may take an unsigned copy of this form home to reread and discuss with your family, friends and healthcare provider or doctor.
- You or your child may ask the study doctor and the site staff any questions

Thank you for taking the time to consider this study.

Information in this Informed Consent Form may be confidential to the Sponsor. The Sponsor is sharing this information with you or your child so you or your child will know details about the study as you decide whether to participate in the study. We ask you to consider this private information when discussing details about the research study with people other than your/child's healthcare provider(s), family and friends.

Why is this study being done?

The Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) disease commonly called Coronavirus (COVID-19) emerged in the human population in Wuhan City, Hubei Province, China in December 2019. The World Health Organization (WHO) declared COVID-19 a pandemic on 11 March 2020. The burden of COVID-19 has been very bad with more than 5.54 million deaths and over 328 million confirmed cases worldwide as at January 2022 and more than 7 million cases and 160,804 deaths in Africa as of 17 January 2022. The COVID-19 pandemic has

caused major social, educational and economic disruptions. Despite public health measures of isolation, quarantine, social distancing, and handwashing to stop the spread of the virus, and the rapid development and worldwide use of COVID-19 vaccines, the worldwide burden of coronavirus infections and disease remains substantial. There is therefore a continued urgent need to develop effective and safe vaccines to make them available across all countries including in Africa.

Despite the rapid successes in vaccine development, the WHO reports, and US Food and Drug Administration (FDA) reports written after assessing the COVID-19 vaccines for approval for Emergency Use, have shown that the COVID-19 vaccines require additional information which was not available from the big vaccine studies. For example, information on safety and how the primary and booster vaccines work in certain populations such as children and adolescents less than 18 years of age, pregnant women, and immunocompromised individuals like people with HIV/AIDS who are at higher risk of severe COVID-19 disease is required. Africa is especially at risk given the high number of HIV/AIDS patients in countries like Kenya where some places the rate of HIV infection is over 20% like in western Kenya.

This study is therefore being done to test the new Janssen COVID-19 vaccine called Ad26.COV2.S1 and the Novavax COVID-19 vaccine called Novavax for adults or Novavax vs mRNA (Moderna mRNA-1273 or Pfizer/BNT) vaccine for adolescents as booster doses in both HIV positive and negative adolescents and adults. Doctors and scientists hope it will prevent or lessen the severity of COVID-19 disease. The Coronavirus is passed from person to person primarily by small droplets from the nose or mouth when an infected person coughs, sneezes or speaks. Most people who are infected have mild symptoms such as fever, cough, tiredness, loss of taste and smell, but some people have severe disease and can even die.

The new Janssen COVID-19 vaccine, Novavax COVID-19 vaccine and mRNA (Moderna mRNA-1273 or Pfizer/BNT) COVID-19 vaccines may help to prevent disease by allowing the human body to develop an immune response against the Coronavirus that causes the disease. This defensive response is a way you/child's body fights infections. This study will help determine if the Janssen COVID-19 vaccine, Novavax COVID-19 vaccine and mRNA (Moderna mRNA-1273 or Pfizer/BNT) COVID-19 vaccines are safe for humans and if each vaccine causes an immune response that protects against COVID-19 disease.

The main purposes of this study are to investigate:

- If the Janssen COVID-19 vaccine and Novavax COVID-19 vaccine for adults or Novavax vs mRNA (Moderna mRNA-1273 or Pfizer/BNT) COVID-19 vaccine for adolescents causes an immune response that protects against COVID-19 disease
- If the Janssen COVID-19 vaccine and Novavax COVID-19 vaccine for adults or Novavax vs mRNA (Moderna mRNA-1273 or Pfizer/BNT) COVID-19 vaccine for adolescents is safe

- The side effects caused by the Janssen COVID-19 vaccine and Novavax COVID-19 vaccine for 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 for 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.

The study will use a mix and match method. Both adults and adolescents who have previously received Covid-19 vaccinations by the country's national vaccination program, will be allocated by chance to two groups to 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 booster doses are given by injection (shot).

Throughout this document, when the words "study vaccine" are used, they can mean Janssen COVID-19 vaccine or Novavax COVID-19 vaccine or mRNA (Moderna mRNA-1273 or Pfizer/BNT) COVID-19 vaccine

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

If you join the study, you will be in it for about 18 months or if your child joins the study, they will be in it for about 12 months. During the study we will collect blood samples and nasal swabs. If you or your child become sick with COVID-19 (and as explained later, you or your child cannot get COVID-19 from the vaccine), the study staff will monitor you or your child daily and request that you or your child provide extra nasal swabs.

During the study, the Sponsor may learn new information about the study vaccine such as risks. Your /child's study doctor will tell you or your child as soon as possible about any new information that might make you or your child change you/child's mind about being in the study. It is possible that you or your child will benefit from participating in this study because of the results of how the vaccine works to prevent COVID-19 disease from other countries. There is a small chance you or your child may have a bad reaction to the vaccine.

Taking part in this study is your/child's choice. You or your child may choose to not participate in this study, in which case you or your child will not lose any access to any medical care or other benefits to which you or your child are otherwise entitled. There will not be any penalty if you or your child decide not to take part.
This study is funded by the Coalition for Epidemic Preparedness Innovation (CEPI), which is a global partnership that was launched in 2017 to support development of vaccines to stop epidemics like COVID-19.

WHAT HAPPENS DURING THE STUDY?

The study is divided into 2 parts as shown below: 1) Screening Period, 2) Main Study Period that includes Booster Vaccination and Follow-up Periods. The Main Study Period is about 12 months for children and 18 months for each adult participant.

Screening Period	**Main Study Period**	
	Booster Period	**Follow-up Periods**
▪ Screening is the process you or your child undergo to determine if you or your child can participate in the study. ▪ You or your child will undergo informed consent ▪ You or your child will undergo a medical assessment ▪ You or your child will undergo HIV and laboratory tests for blood picture, liver and kidney functions and pregnancy test for females ▪ You or your child will have a rapid test for COVID-19	▪ You or your child will undergo a medical assessment and pregnancy test for females ▪ You or your child will have a rapid test for COVID-19 ▪ You will be randomized to receive either the Novavax or Janssen booster dose ▪ Your child will be randomized to receive either the Novavax or mRNA (Moderna mRNA-1273 or Pfizer/BNT) booster dose ▪ You or your child will have blood draws for immune response testing to see how the vaccine works in your/child's body ▪ You or your child will be followed up for long term safety and COVID-19 monitoring from Day 7	▪ You or your child will undergo a medical assessment ▪ You or your child will have a rapid test for COVID-19 ▪ You or your child will have a safety follow up assessment after the booster vaccination for 7 days ▪ You or your child will have blood draws for immune response testing to see how the vaccine works in your/child's body ▪ You will be followed up for long term safety and COVID-19 monitoring from Day 0, Day 28, Day 85, months 6, 12 and 18. ▪ Your child will be followed up for long term safety and COVID-19 monitoring from Day 0, Day 28, Day 85, months 6 and 12.

Some participants will have extra tests and procedures

There is one group of participants in Kenya that will have extra blood draw for an Immune Response test of the immune cells in the body. This group will include subset of 30 HIV (-) Adults/Primary vaccine/platform and 60 HIV (+) Adults/Primary vaccine/platform which will total to about 120 HIV (-) participants and about 240 HIV (+) participants. The reason for this group is so researchers can take a closer look at their immune responses to the study vaccine. The study staff will tell you or your child if you or your child are included in this group.

WHAT WILL BE DONE DURING THE STUDY VISITS?

Study procedures and activities

During the study, you or your child will have your/child's height, weight, blood pressure, heart rate, and body temperature measured, and be asked to answer questions about your/child's general health, medical history and the medications you or your child take. You or your child will be provided with a thermometer to measure body temperature through the mouth and a ruler to measure redness and/or swelling caused by the injection. The table below explains some other procedures that are part of the study. It is possible that certain on-site study visits will be replaced by telemedicine visits (a remote visit that is done by a phone call) or home visits by study staff supporting home health visits (if applicable).

Procedure	What is it?	When is it done?
Nasal Swab Testing	A cotton swab will be inserted in your/child's nose and rotated to collect a sample of your/child's nasal secretions. You or your child may experience slight discomfort or tickling in the nose with this procedure. It may cause a nosebleed.	Visits 2,4,5,6,7,8 and as instructed if you or your child experience COVID19-like symptoms
Paper Diary	You or your child will be asked to respond to questions about your/child's health using a paper diary questionnaire after the booster vaccination. Participants with verified COVID-19-like illness will have samples collected in the field or be asked to visit the site for the collection of samples for COVID-19. You or your child will be reminded to complete daily reporting of your/child's COVID-19 disease self-directed assessment (whenever test is positive) of symptoms in the paper diary and to inform the site if you seek medical care. Site staff will show you or your child how to complete the paper diary questionnaires. It will take you or your child a few minutes to complete most questionnaires. It may take about 15 minutes to complete questionnaires when you or your child experience changes to your/child's health. You or your child may receive text messages or telephone calls as reminders to complete these questionnaires. You or your child may have a caregiver or site staff assist with completion of questionnaires as needed.	After the booster dose, you or your child will be asked to answer questions on possible signs and symptoms experienced after the vaccination. For example, fever, tiredness, pain and so on. During the Main Study Period, you or your child will be asked to complete daily reporting of your/child's COVID-19 disease self-directed assessment (whenever test is positive) of symptoms in the paper diary and to inform the site if you seek medical care.

	There are 2 types of paper diary questionnaires: For all participants to report reactions after vaccination (including measuring body temperature and measuring any redness and/or swelling where they received the vaccine); For all those who develop symptoms of COVID-19 and test positive, to provide information about the signs and symptoms they experience (including measuring body temperature, pulse oximetry and heart rate);	All participants will report reactions after vaccination. This will be done on a daily basis for 7 days starting from the day of vaccination. If you or your child develop signs and symptoms of COVID-19, you or your child are asked to report this immediately via the application. In addition, you or your child will be asked to respond daily to questions about the symptoms you or your child have.
Procedure	**What is it?**	**When is it done?**
Blood draw/tests	The study doctor or staff will draw blood from a vein in your/child's arm. You or your child may have pain, get a bruise or irritation at the place where the needle goes into your/child's 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 105 mL (about 10 Tablespoons) for the majority of study participants. For a smaller group of up to 90 adult participants in each of the 3 vaccine types (platforms) in Kenya, an additional 40 mL (about 4 Tablespoons) will be taken to test for other Body Immune Cell Responses. Should you or your child become sick for any reason such as COVID-19 disease, Malaria or other illnesses, the doctor or health provider may ask for additional blood draws for you/child's medical assessment and treatment.	All adult participants will have blood drawn at Visits: 1, 2, 3,4, 5, 6, 7 and 8 and children up to visit 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 or your child may need to repeat a blood test.
	You or your child may be asked to repeat a blood test if there are safety or technical issues with the initial draw. Your/child's blood will be used to check • For confirmation of COVID-19 infection • Your/child's immune response to the study vaccine • Assessment of your/child's health and safety during the study Positive COVID-19 tests will be reported to applicable health authorities.	

Urine sample	If you or your child are a female who could get pregnant, we will collect a urine sample from you to check for pregnancy.	Visit 1 and Visit 2

What will happen regarding the Home Health Care Visits?

The study staff will collect your/child's contact details (name, physical address, telephone number). The information will then be shared with the assigned study staff who will perform the study home visits. The study staff will contact you or your child to schedule the visit. The study staff will arrive at your/child's preferred location and will perform the procedures and capture any visit data using study documents. The study staff may also request information regarding your/child's current and past health issues. Your/child's study doctor or other study staff will review the visit data and may request that you or your child visit the study site for a follow-up visit if needed.

STUDY RESPONSIBILITIES

To participate in the study, you or your child have responsibilities.

Do	**Do not**
• Give correct information about your/child's health history and health condition. • Tell the study staff about any health problems you or your child have during the study. Note: You or your child should contact the study staff as soon as you or your child start experiencing COVID-19 like symptoms. • Talk to your/child's study doctor or study staff before getting any other licensed vaccines (such as rabies vaccine, ebola vaccines). • Tell the study staff about any new medicine or drug you or your child take during the study, including over-the-counter drugs (for example, to treat side effects after the injection). Also, tell the study staff about any changes to your/child's ongoing medicines or drugs. • Provide all required samples, e.g., nasal swabs, and blood samples. • Attend all study visits.	• Do not take part in any other medical research studies. • Do not receive COVID-19 vaccines other than the one provided through this study. • Do not get pregnant within 3 months of receiving study vaccine. • Do not donate blood, and blood products from time of the study vaccine administration until 3 months after receiving the study vaccine.

STUDY VACCINE/OTHER MEDICATIONS

What is the Janssen COVID-19 vaccine (Ad26.COV2.S1)?

The Janssen COVID-19 study vaccine is made by Johnson and Johnson Pharmaceuticals from a type of common cold virus called Adenovirus. The adenovirus used to make this vaccine has been weakened so it cannot multiply and cause a cold.

The Janssen COVID-19 study vaccine includes a protein material from the COVID-19 Coronavirus called a spike protein which looks like the crown of a king or queen. When the study vaccine is injected into your/child's body, the protein material triggers our bodies to make an immune response against these spike proteins. This immune response is our body's way of fighting the infection. You or your child cannot contract COVID-19 from the study vaccine.

Janssen COVID-19 vaccine is an "experimental vaccine" in this study, even though it has received emergency use authorization from the World Health Organization (WHO) and Government Regulatory Authorities in the US, Europe and even in Africa. Additional information about the safety, immune response and how the vaccine works is still being collected in studies such as ours. The vaccines for this study can only be used in this research study and are not approved for use outside the study participants.

What is the Novavax COVID-19 vaccine (Novavax)?

The Novavax COVID-19 study vaccine is made by the Serum Institute of India and includes genetic material from the COVID-19 Coronavirus. When the study vaccine is injected into your/child's body, the genetic material from the Coronavirus gets "translated" to produce so called 'spike proteins' which are small bits of protein specific to COVID-19. Our bodies then make an immune response against these spike proteins. This immune response is our body's way of fighting the infection. You or your child cannot contract COVID-19 from the study vaccine.

Novavax COVID-19 vaccine is "experimental vaccine" in this study. It has received emergency use authorization in Indonesia and additional emergency use authorization applications have been made to the World Health Organization (WHO) and Government Regulatory Authorities in the US, Europe and even in Africa. Additional information about the safety, immune response and how the vaccine works is still being collected in studies such as ours. The vaccines for this study can only be used in this research study and are not approved for use outside the study participants.

What is the Pfizer–BioNTech COVID-19 vaccine (BNT162b2)?

The Pfizer–BioNTech COVID-19 vaccine, BNT162b2, is made by Pfizer from genetic material (mRNA) from the COVID-19 Coronavirus. It has received use authorization from the World Health Organization (WHO) and Government Regulatory Authorities in the US, Europe and even in Africa. Additional information about the safety, immune response and how the vaccine works will be collected in studies such as ours. The vaccines for this study can only be used as a booster in this research study and are not approved for use outside the study participants.

What is the Moderna mRNA-1273?

The Moderna's mRNA-1273 COVID-19 vaccine is made by Moderna from genetic material (mRNA) from the COVID-19 Coronavirus. It has received use authorization from the World Health Organization (WHO) and Government Regulatory Authorities in the US, Europe and even

in Africa. Additional information about the safety, immune response and how the vaccine works will be collected in studies such as ours. The vaccines for this study can only be used as a booster in this research study and are not approved for use outside the study participants.

What injection will I receive?
The study will use a mix and match method. Adults will be allocated by chance to two groups to 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 while Adolescents will be allocated by chance to two groups to receive either a booster dose of Novavax COVID-19) vaccine at day 0 or a booster dose of mRNA (Moderna mRNA-1273 or Pfizer/BNT) COVID-19 vaccine at day 0.

A computer will randomly assign you or your child to either group by chance, like flipping a coin. You or your child will have a 50% chance of being put in either group as shown in the table below:

Mix and Match Study Vaccination Groups for Adults

Vaccine Platform for Primary Series	**HIV (+) adults (age 18-64)**	**HIV (-) Adults (age 18-64)**	**Booster vaccination (5-7 months) 1:1***
mRNA (Moderna mRNA-1273 or Pfizer/BNT)	450	100	Janssen Ad26COVS1
			Novavax
Adenovector 26 (Janssen Ad26COVS1)	450	100	Janssen Ad26COVS1
			Novavax
Inactivated whole virus (Sinopharm-BIBP or Sinovac)	450	100	Janssen Ad26COVS1
			Novavax
Total	**1,350**	**300**	**Maximum 1,650**

Mix and Match Study Vaccination Groups for Adolescents

Vaccine Platform for Primary Series	**HIV (+) adolescents (age 12-17)**	**Booster vaccination (≥5 months) 1:1**
mRNA (Moderna mRNA-1273 or Pfizer/BNT)	150	Novavax
	150	Moderna mRNA-1273 or Pfizer/BNT**
Total	**Maximum 300**	**Maximum 300**

*Booster vaccination for adolescents at ≥5 months after the last primary vaccination series.

During the study, you, your child or the study staff will not know which group you or your child are in. In a medical emergency, the study staff can quickly find out which group you're in.

How is the study vaccine given?
The study vaccine is given by injection. The needle is put into the muscle in your/child's upper arm. When possible, the injection will be given in the arm you or your child use less. This will be done on Day 0.

You or your child 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 or your child to fill every day for the next 7 days at home. You or your child will bring the completed study diary to the study clinic during your/child's next visit.

What other options are there besides this study?
Taking part in this study is voluntary. You or your child do not have to take part in this study. There are currently some approved vaccines for COVID-19. There may be other studies in your/child's area testing different vaccines against COVID-19. Your/child's study doctor or study staff will discuss these options, and their risks and benefits, with you or your child.

What about my current medicines?
The study staff will ask about all prescription and over-the-counter medicines that you or your child are taking. This includes vitamins and herbs. The study staff will let you or your child know if there are medications you or your child are not allowed to take during the study.

WHAT ARE THE POSSIBLE SIDE EFFECTS AND RISKS OF PARTICIPATING?

Potential Discomforts, Side Effects, and Risks Associated with Janssen COVID-19 vaccine, Novavax COVID-19 vaccine and Pfizer/Moderna vaccines.

Vaccines similar to Janssen COVID-19 vaccine have been given to participants in studies designed to prevent HIV (Human Immunodeficiency Virus), Ebola, malaria among others. As of 31 December 2020, vaccines like Janssen had been used to vaccinate more than 193,831 participants in clinical studies and vaccination programs, including in Kenya, Rwanda and the Democratic Republic of the Congo.

Several clinical studies of the Janssen COVID-19 vaccine have also been undertaken in more than 70,000 adult participants. On 2nd April 2021, Janssen started enrolling adolescents 12-17 years old as well. The Novavax COVID-19 vaccine has also been evaluated in several clinical studies in adults with more than 50,000 participants taking part. The Pfizer and Moderna COVID-19 vaccines have also been evaluated in several clinical studies in adults and adolescents with thousands of participants taking part. Both vaccines are currently recommended for use in adults and adolescents by the WHO, US CDC, FDA, among others. The Pfizer vaccine has since been administered to over 25 million vaccine doses in adolescents.

Pain, tenderness and redness at the injection site, headache, chills, joint pain, muscle pain, tiredness, generally not feeling well, nausea and fever have been seen with these study vaccines. These reactions usually start within 1 to 2 days after the injection and most of the reactions get better within 1 to 3 days.

All vaccines can cause side effects. Problems that are not expected may happen and these may be life-threatening. If you or your child have any side effects or problems during this study, please tell your/child's study doctor right away. Please tell the study staff if you or your child are taking any medication.

There may be risks associated with the study COVID-19 vaccines that we don't know about yet. If we learn new information about the study vaccine and risks associated with it, we will tell you or your child.

Risks and possible side effects of vaccines in general

Vaccine injections can cause:

- Itching, arm discomfort, pain, soreness, redness, hardness, bruising and swelling where you or your child receive the injection
- Fever
- Chills
- Rash
- Itching in other areas of your/child's body
- Aches and pains
- Muscle and joint pain
- Nausea and Vomiting
- Headache
- Dizziness
- Feeling very tired
- Fainting

These side effects usually last about 2 to 3 days. Rarely, people may have more severe side effects that limit their normal activities or make them go to the doctor.

Allergic reactions

You or your child could have an allergic reaction to a vaccine, including a rash, sudden change in blood pressure (making you or your child feel dizzy or lightheaded), fast pulse, sweating, or difficulty breathing. **Some allergic reactions can be life-threatening**. The study staff will watch you or your child for at least 30 minutes after your/child's injection.

Always tell the study staff if you or your child have ever had a bad reaction to any injection or vaccine. They can give you or your child medicines in the clinic to treat serious allergic reactions. If you or your child think you or your child is having a severe allergic reaction after you or your child leave the study site, contact the study doctor or an emergency number and get medical help right away.

Risk of testing positive for COVID-19 antibodies

If you or your child receive the study COVID-19 vaccines, your/child's body may have an immune response to the specific coronavirus proteins that are part of the vaccine. This immune response will not affect any results of COVID-19 tests, whether taken as part of the study or outside of the study, that are obtained from a swab of your/child's nose (or from your/child's throat)—as these tests tell you or your child if you or your child currently have COVID-19 virus in your/child's body. Some tests, however, are done to check if you or your child have previously been infected with COVID-19—these tests check for antibodies. These antibody test results might also be positive if you or your child received the COVID-19 vaccine, even if you or your child were never truly infected with the virus. For this reason, we recommend that you or your child do not seek testing outside of this study, but rather speak with study staff if you or your child need to get tested. The study staff will provide you or your child with additional information and help you or your child get the right test.

If you or your child become pregnant during or after the study and have antibodies in response to the vaccine, we don't know if the antibodies can be passed to your/child's baby. We do know that antibodies from other vaccines, like tetanus vaccine, do get passed to the baby. For most babies, antibodies passed from the mother last for about six months. We do not know the effect of the study vaccine on babies before they are born, or on breastfeeding babies. The WHO recommends the use of COVID-19 vaccines in breastfeeding mothers and does not recommend that breastfeeding be stopped after vaccination.

Other potential risks:

The study team will make every effort to ensure that information for this study obtained from you or your child is kept confidential. All efforts will be made to protect your/child's information to help prevent unauthorized access to your/child's research data.

COMMON QUESTIONS ABOUT JOINING THE STUDY

Will I be paid?

The sponsor has made provision to reimburse you and your child for out-of-pocket expenses such as travelling to and from the study site and other miscellaneous costs, such as time and inconvenience, as a result of study participation.

You and your child will receive Ksh 1000 for inconvenience and time and about 500 Kenya Shillings as transport reimbursement depending on the local rates which will total to about Ksh 1500 per planned visit to reimburse you for such expenses. For unscheduled visits, you and your child will receive Ksh. 300 as transport reimbursement. If your study-related costs exceed the specified amount and you have proof of such expenses, please discuss them with your child's study doctor.

Who pays for the study vaccine and tests?
There are no costs to you or your child to be in the study. The Sponsor will pay for the study vaccine and the tests that are part of the study.

The study site may offer you or your child medical care for acute illnesses or pay for doctor visits, treatments, or tests that are not part of this study. This may include visits/hospitalizations for COVID-19.

You or your child should continue to utilize your/child's health insurance (if you or your child have), or your government health plan responsible for paying for routine care you or your child would receive whether or not you or your child are in the study. You or your child may talk to the study staff and inform them if you or your child have other medical covers.

Can the study investigator remove me from the study?
Yes, the study investigator has the right to remove you or your child from the study at any time without your/child's consent. This decision may occur if:

- It is in your/child's best medical interest to do so
- The study is canceled by the Regulatory Authority or Ethics Committee in your/child's country or the sponsor
- You or your child are no longer following the study requirements or procedures

The study staff will discuss the reasons for removing you or your child from the study, other treatment or research options, and plans to follow up with you or your child for side effects.

Can I change my mind about participating?
Yes. You or your child can agree to be in the study now and change your/child's mind **at any time and for any reason**. There will not be any penalty or loss of benefits to which you or your child are otherwise entitled if you or your child leave the study early. Your/child's decision will not change any regular care that you or your child normally receive. Please talk to your/child's study doctor or study staff before changing your/child's mind about participation. If you decide to leave the study early, there may be risks with this decision. You or your child should discuss these risks with your/child's study doctor or study staff. You or your child may be asked to return to the study clinic for a final medical assessment before you or your child leave.

What if I get COVID-19 during the study?
When you or your child enroll into the study, you or your child will be asked to provide the name of your/child's regular doctor and the hospital you or your child would likely seek care at if you or your child become seriously ill. This is to ensure we follow you or your child to check your/child's health. You or your child should contact the study staff as soon as you or your child start experiencing COVID-19-like symptoms. Study staff will monitor your/child's health and may visit you or your child in your home. If you or your child seek health care for COVID-19 by a nurse or doctor at a clinic, or hospital, we ask that you or your child 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.

What happens if I stop the study early?
If you or your child stop the study early, the study staff will ask you or your child to do final study visit before you or your child exit. This is to check your/child's health. This information will be added to your/child's study record. If you or your child do not want the study doctor to continue monitoring your/child's health after you or your child stop taking the study vaccine, you or your child will be asked to indicate this by informing the study doctor or study staff. However, it is recommended that you or your child continue to have the study doctor or study staff follow you or your child for safety for a period of time.

If the study staff is unable to contact you or your child by conventional means (e.g., clinic visit, telephone), he/she may also contact you or your child by reaching out to your/child's emergency contact or by locator information taken during your/child's first visit, as permitted by local regulations to find out about your/child's health status. By signing this consent form, you or your child agree that this information can be obtained and added to your/child's study record.

If you or your child have side effects from the vaccine or study procedures after you or your child stop the study early, the study doctor or staff may contact your/child's other doctors or healthcare providers who you see regularly to get information about your/child's side effects. By signing this consent form, you or your child agree that this information can be obtained and added to your/child's study record.

If you or your child stop the study early and withdraw your/child's consent at any time, you or your child agree to allow the use of information collected about you or your child for the purpose of the study up to the point of your/child's consent withdrawal. The Sponsor will continue to collect information from you or your child as described in other sections of this Informed Consent Form. The Sponsor will not collect any new information from you or your child for any parts of the study from which you or your child have withdrawn unless you or your child have a side effect related to the study.

Can I take the study vaccine after the study is over?
After you or your child complete the trial, you or your child will no longer receive the study vaccines. However, you or your child may receive other COVD-19 vaccines as will be determined after consultation with the national health authorities in your country.

What are the benefits of joining this study?
You or your child will undergo a medical examination as part of this study and you or your child will be informed about your/child's current health. If you receive the study vaccine, your/child's body may or may not produce an immune response that protects you or your child against COVID-19. There may be no direct medical benefit to you or your child for participation in this clinical study. Your/child's participation, however, will provide information about the study vaccine and may help future patients and the general population.

WHAT IF SOMETHING GOES WRONG OR YOU OR YOUR CHILD GET HURT?
If you or your child are hurt as a direct result of taking part in this research project, the sponsor will pay for health care to treat the illness/injury. If you or your child are injured by a medicine or treatment that you or your child would not have been given outside our study, you or your child may be entitled to compensation. The sponsor has insurance to cover the costs of research-related injuries. This is provided that you or your child followed all the instructions and advice of the study doctor and did nothing to cause or contribute to the research-related injury. By signing this form, you or your child do not give up any legal right you or your child may have. The Principal Investigator for this study, Dr Lucas Tina can give you or your child more information.

Free medical care for research-related injuries will be provided at the Clinical Research Centre. If you or your child require medical care beyond the abilities of the Clinical Research Centre, we will transport you or your child to an appropriate medical facility and pay for your/child's care there.

By signing this consent form, you or your child do not give up any of your/child's legal rights in the event of an injury.

BIRTH CONTROL AND PREGNANCY DURING THE STUDY
The safety of the Novavax COVID-19 vaccine, Janssen COVID-19 vaccine mRNA (Moderna mRNA-1273 or Pfizer/BNT) COVID-19 vaccine in pregnancy are still being studied. Evidence continues to build showing that COVID-19 vaccination before and during pregnancy is safe, effective, and beneficial to both the pregnant person and the baby. The benefits of receiving a COVID-19 vaccine outweigh any potential risks of vaccination during pregnancy. However, women who are pregnant, breastfeeding, planning on becoming pregnant, or who cannot provide a credible history of reliable contraceptive practices, will therefore not receive the COVID-19 vaccines as part of the study.

Female Participants Who Cannot Get Pregnant:
If you are postmenopausal for at least 12 months or have had surgery and therefore you or your child cannot get pregnant, this section about contraceptive use does not apply to you or your child.

Female Participants Who Can Get Pregnant:
If you are female and can get pregnant (meaning that you or your child are neither postmenopausal for one year nor surgically sterile) and sexually active, you or your child must avoid getting pregnant in order to take part in this study. You or your child will be required to agree to use an approved method of birth control (as described below) prior to the study vaccination and continuing for 3 months after the administration of study vaccine. In addition, you or your child will need to have a negative pregnancy test before booster vaccination.

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.

Please talk to the study staff about specific questions concerning acceptable birth control methods and he/she must approve the method you or your child use before you or your child can enter the study.

If you or your child are a female who can get pregnant, you or your child must agree to have a urine pregnancy test at screening and immediately prior to each study vaccine administration to demonstrate that you or your child are not pregnant.

If you or your child suspect that you or your child have become pregnant during the study, you or your child must notify your/child's study doctor or study staff immediately. If you or your child become pregnant during the study, you or your child may continue in other study procedures (you or your child may have blood drawn for safety and immune response testing), if the investigator decides it is safe for you or your child and your/child's unborn child. The study doctor will collect information about your/child's pregnancy and the health of your/child's baby. If you or your child

do not wish to be followed, you or your child can withdraw your/child's consent at any time by informing your/child's study doctor.

Male Participants Whose Partner Can Get Pregnant:
If your/child's partner becomes pregnant during the study, you or your child should tell the study doctor immediately. Your/child's partner will be asked for permission to allow the study doctor to follow up and collect information about their pregnancy and the health of the baby. It is entirely voluntary. Your/child's partner does not have to provide any information.

SAMPLES COLLECTED FOR SCIENTIFIC RESEARCH

What happens to the samples collected from me?
The Sponsor may use any of your/child's samples collected during this study to:

- Understand how the Janssen COVID-19 vaccine, Novavax COVID-19 vaccine and mRNA (Moderna mRNA-1273 or Pfizer/BNT) COVID-19 vaccine works, or why it may cause side effects
- Better understand COVID-19 disease
- Understand why people may respond differently to the study vaccine

To protect you or your child's confidentiality, your/child's samples will be labeled with the study number and participant number. No personal identifiers are used (such as name, initials, or social security number). The scientists doing the research will not know your/child's identity.

You or your child's clinical samples for safety tests such as liver, kidney, blood picture, HIV, urine pregnancy and COVID-19 illness will be tested at the Kisumu County Referral Hospital, Lancet Pathologists Laboratory and KEMRI CDC Kisumu Laboratory.

You or your child's blood and nose samples for immunity testing may be sent to the Sponsor and CEPI Central Lab at International Centre for Diarrhoeal Diseases Research in Bangladesh (ICDDR-B). Researchers working with the Sponsor are not allowed to share samples with anyone who is not authorized by the Sponsor.

You or your child will not be paid for any use of your/child's samples or results, or for inventions made from research on them. You or your child are providing your/child's samples, for use by the Sponsor. The Sponsor (and research partners, where applicable) will own the use of the results, treatments, or inventions that can be made from this research.

Your/child's collected samples will continue to be analyzed as described in this form unless you or your child specifically ask for your/child's samples to be destroyed. This is to protect the quality of the study.

Samples Used for Future Research

After the end of the trial, any unused part of the blood or respiratory samples will be securely stored at the VIBRI, or CEPI Central Lab (ICDDR-B) up to 10 years. These samples are being retained in long-term storage to support answers to regulatory questions related to the vaccines licensing and the potential review of the trial results. You or your child will be asked to consent for the future use of these samples beyond the scope of the testing outlined in this informed consent, but consent for future use will not be required for participation in this study. You or your child will be asked to state in this Informed Consent Form whether they will permit the future use of any unused stored samples for other tests not related to study objectives. If you or your child refuse to give permission, the samples will not be used for any testing other than that directly related to this trial. If you or your child agree to this use, you or your child will not be paid for giving permission. The samples will not be directly linked to you or your child to ensure confidentiality. The aim of any possible future research is unknown today and may not be related to this particular study. It may be to improve the knowledge of vaccines and their mechanism of action, the knowledge of infectious diseases, or to improve existing tests or develop new tests to assess vaccines. Genetic tests are not performed in this study.

You or your child may opt out of future use of your/child's samples or withdraw your/child's consent at any time by notifying your/child's study doctor. If you or your child withdraw consent for future use of your/child's samples, your/child's samples will be destroyed after they are no longer required for the main study. This will not affect your/child's access to the care, or medicine you or your child would otherwise be getting. This can be done at any time and for any reason.

HOW IS MY PRIVACY / CONFIDENTIALITY PROTECTED?

The study staff and the Sponsor will manage your/child's personal data (information about you or your child) in compliance with the study regulations. In this study, we will record some personal information about you or your child. We need some of this information to show that you or your child agreed to take part in this study and that you or your child meet the study requirements.

We will keep your/child's personal information confidential. Here is how we protect it:

- Your/child's name and contact information are kept in a locked cabinet or rooms with restricted access. Only the study team can access it.
- On study forms, we will use an identification number in place of your/child's name.
- The information using your/child's identification number in place of your/child's name is put into computers. These are password protected.

The study team keeps a link between your/child's name and your/child's study number in case you or your child need to be contacted in the future. After 10 years we will destroy the link and any documents that identify you or your child.

What personal data will the study staff collect?
If you or your child join this study, the study staff will collect and use your/child's personal data that may include information about your/child's health.

The study staff will also collect, record, and use personal information about you or your child, for study purposes only. Your/child's personal information collected may include:

- Demographic information such as your/child's name, your/child's study ID #, home address, telephone/mobile number, date of birth, and gender which will be entered into study forms;
- Contact information about your/child's emergency contact; and caregiver, if applicable
- The name of your/child's regular doctor or healthcare provider
- Sensitive information about your/child's physical or mental health or condition
- Medical records (from any doctor, hospital or other healthcare provider)
- Information from the questionnaires you or your child are asked to complete
- Information created or collected during the research. This could include your/child's medical history, and dates or results from any physical exams, laboratory tests or other tests.

All information which is collected about you or your child for the purposes of medical, or regulatory activities related to the study research or to analyze the study data will be identified only by your/child's subject number. Only the study doctor and the study team will have access to information that can link you or your child to the subject number; this information will not be shared outside of the study team unless necessary for safety purposes.

Who else will have access to your/child's personal information?
Information about your/child's taking part in this study will remain confidential. Only the Clinical Research Centre staff have access to your/child's study records. They are not allowed to share any personal information. All files will be kept in locked cabinets or rooms with restricted access when they are not in use. The information we collect may be reviewed by:

- Representatives of the Scientific and Ethics Review Committees;
- Representatives of ACE Research and the sponsor;
- Representatives of the Country Drug Regulatory Authority (such as, PPB).
- Representatives of the Coalition for Epidemic Preparedness Innovation (CEPI)
- Representatives of the Ministry of Health in your country.

They are not allowed to share any personal information about you or your child. Every effort will be made to keep the records as confidential as possible within the provisions of the law. All data and medical information obtained about you or your child as an individual will be considered important and held in confidence. All the above representatives are bound by rules of confidentiality not to reveal your/child's identity to others.

These people will be granted direct access to your/child's original medical records for verification of clinical study procedures and/or data, without violating your/child's confidentiality, to the extent permitted by the applicable laws and regulations. By signing this informed consent form, you or your child authorize such access.

Records identifying you or your child will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, your/child's identity will remain confidential.

You or your child may decide not to give permission for the use or disclosure of your/child's protected health information for the study. In that case, you or your child will not be able to participate in the study. This is because the study staff and/or the study doctor would not be able to collect the information needed to evaluate the study vaccine.

Remote access to your/child's records at the study site
Representatives of the Sponsor (e.g., monitors and auditors) may use an electronic tool to access non-identifiable personal study data remotely. This electronic tool provides a secure electronic gateway between the study doctor and staff's computer system and the computer of the representatives of the Sponsor, who may be located outside of your country of residence. This minimizes the risk that anyone else might be able to access the information.

How will Your/child's Coded Data be shared and transferred by the Sponsor?
The Sponsor may share Your/child's Coded Data with its affiliates, regulatory authorities (such as the Kenya Pharmacy and Poisons Board), the ERC, authorized service providers and, with select investigators and scientists conducting scientific research, that is compatible with research related to this study including statistical purposes. Your/child's Coded Data may also be shared with scientific journals so the study results can be reviewed by independent scientists and to ensure the accuracy of results. Your/child's identity will not be revealed in any of these cases.

The Sponsor will protect Your/child's Coded Data as far as the law allows and will keep and supervise the information collected about you or your child only for as long as needed.

Sharing of your/child's anonymized data by the Sponsor
Anonymized means your /child's data and samples will be stripped of your/child's participant number as well as of any other information that could identify you. The anonymized data and samples may be shared only for scientific research as allowed by law.

How long will your/child's personal data be stored by the Sponsor?
Records containing your/child's personal data will be retained at the study site for a period of at least 10 years as allowed per applicable laws for the identified use.

What rights do you or your child have concerning your/child's personal data?
If you would like to review, correct, delete, or make other requests about your/child's personal data, you or your child should contact your/child's study doctor at the phone number(s) listed above on the first page.

You or your child may not be able to review some of the data until after the end of the study, and a request to delete your/child's personal data cannot be fulfilled where regulations and laws that apply to clinical research require your/child's personal data to be retained.

You or your child can ask your/child's study doctor to send any questions, concerns or complaints you or your child may have to the Sponsor.

What if I change my mind and do not want my information used or disclosed?

- If you or your child no longer want to share your/child's protected health information, you or your child may cancel your/child's permission at any time by writing to the study staff and/or the Study doctor at the address listed above on the first page.
- If you or your child cancel your/child's permission after you or your child have started in the study, the study staff and the Study doctor will stop collecting your/child's health information unless you or your child have a side effect related to the study. Although they will stop collecting new information about you or your child, we may need to use and share the information we have already collected to evaluate the study results, unless you or your child has requested that the information be destroyed. If you or your child start the study and then cancel your/child's permission, you or your child will not be able to continue to participate in the study or receive any treatment as part of the study. This is because the study staff and/or the Study doctor would not be able to collect the information needed to evaluate the study vaccine.
- If the study doctor or Sponsor ends your/child's participation, or if you or your child decide not to continue, you or your child will be asked to return to the study doctor or study site to have all of the final clinical evaluations and laboratory tests done.
- If you or your child withdraw from the study but do not withdraw your/child's authorization, new health information may be collected until this study ends.
- Your/child's decision to withdraw your/child's authorization will not involve any penalty or loss of access to treatment or other benefits to which you or your child are otherwise entitled.

If you or your child do not withdraw this authorization, it will remain in effect.

HOW DO I LEARN ABOUT THE STUDY RESULTS?
The Sponsor will analyze the data and offer you or your child a summary of the study results after all study participants have completed the study. This may be some time after you or your child have completed your/child's participation in the study. The summary will not include individual results or information that can identify any participants. The summary may be posted on a website or the study staff may be able to give you or your child a written summary.

GENERAL STUDY INFORMATION

Who should you or your child contact for more information?
For more information about the study, your/child's rights, and in the event of a study related injury or side
effect/adverse event, please contact:

Name Principal Investigator: Dr. Lucas Tina
Phone: +254 788 065080

The 24-hour emergency phone number is: +254 788 065080

After you or your child have consulted you/your child's doctor or ethics committee and if they have not provided you or your child with answers to your satisfaction, you or your child should write to the Regulatory Authority at:

Pharmacy and Poisons Board,
P.O. Box: 27663-00506,
Nairobi, Kenya
Email: cta@pharmacyboardkenya.org

It is important that you or your child know that you or your child have the right not to participate without giving a reason and without any penalty or loss of benefits.

If you or your child have questions regarding your/your child's rights as a research participant, you or your child may contact Amref Health Africa in Kenya. This research is being overseen by an Ethics Review Committee ("ERC"). An ERC is a group of people who perform independent review of research studies. You or your child may talk to them at:
Amref Health Africa in Kenya,
Ethics and Scientific Review Committee (ESRC),
P.O Box 30125-00100
Nairobi, Kenya
+254 20 699 4000/+254795746777
esrc.kenya@amref.org

- You or your child have questions, concerns, or complaints that are not being answered by the research team
- You or your child are not getting answers from the research team.
- You or your child cannot reach the research team.
- You or your child want to talk to someone else about the research.
- You or your child have questions about your/child's rights as a research subject.

YOUR/CHILD'S AGREEMENT TO PARTICIPATE

If you or your child agree to join the study, please read and then sign below.

- I have read and understood this information.
- This study has been explained to me.
- All my questions about the study, the Janssen COVID-19, the Novavax COVID-19 and mRNA (Moderna mRNA-1273 or Pfizer/BNT) COVID-19 as experimental vaccines, and possible risks and benefits have been answered to my satisfaction.
- I give permission for my personal information to be collected and kept in the study site and understand that any data shared and used for the study as explained in this consent form will be Coded Data.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study.
- I understand that I will be given a signed and dated copy of this document to keep.
- If a caregiver is required, I consent to allow my designated caregiver to provide support with my study related activities.

I have been informed that the study doctor/staff may inform my regular doctors (if any) or healthcare provider about my participation in this study, and I agree to this. (You or your child may still be in this study even if you or your child do not agree to this.) (Please mark your choice below as X or ✓ .)

Yes	No	Not applicable, I have no other doctors
☐	☐	☐

I give permission for the study staff to collect 2 additional blood samples of about 20 mL each for immune testing at visit 2 and visit 3.

Yes	No	Not applicable, for adolescents and also for adults if the number required per group has been reached
☐	☐	☐

I give permission for the study staff to inform my designated doctor or healthcare provider of any positive COVID-19 test results that I may receive as part of my participation in the study.

Yes	No	Not applicable, I have no primary care doctor
☐	☐	☐

I agree to the shipment of my biological samples to the laboratories named for scientific research tests as described in section "Samples Collected for Scientific Research". (Please mark your choice below.)

Yes ☐ No ☐

I agree to the use of my samples for future scientific research as described in section "Samples Collected for Scientific Research". (Please mark your choice below as X or ✓.)

Yes ☐ No ☐

I agree to participate in the Home Health Care Visit Program which may include the collection of blood samples, urine samples, medical information and other study related procedures from my home or location of my choice and understand that the study site supporting home health visits and as applicable, their study staff, will be provided with my name, address and phone number and will contact me to schedule a Home Health Care visit. (You or your child may still be in this study even if you or your child do not agree to this.) (Your/child's study doctor will let you or your child know if this applies to you or your child.) (Please mark your choice below as X or ✓.)

Yes ☐ No ☐

Based on this information, I volunteer to take part in this study.

By signing this document, I agree to take part in this study, as set out in this information sheet and consent form.

There is no expiration date for this consent form.

Printed name of participant /parent/guardian (personally completed by participant/parent/guardian):	
Date (personally completed by participant/parent/guardian): (DD/MMM/YYYY)	
Signature /Thumbprint of participant/parent/guardian:	

PERSON CONDUCTING CONSENT

Printed name of the person conducting consent:	
Date (personally completed by the person conducting consent):	
Signature of /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:	