Sisonke Open Label Study:
Participants Information and Consent Form

An Open-label, Single-arm Phase 3B study to Monitor the Effectiveness of the Single Dose Ad26.COV2.S COVID-19 Vaccine among Health Care Workers in South Africa

Study name: Sisonke [TOGETHER]

Study number: VAC31518COV3012

Study Sponsor: South African Medical Research Council (SAMRC)

Study Doctor (Investigator): Prof Glenda Gray

Dear Health Care Worker:

You are invited to take part in this research study.

Before you agree to take part in this research study, please read this document carefully.

Before you continue reading this document, here are a few key things for you 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.
- If you join, your participation in this study will last for about 24 months.
- If you join, you will be vaccinated
- You may have blood draws, and other laboratory tests if you are part of the sub-studies.
- You may take an unsigned copy of this form home to re-read and discuss with your doctor/s, family, and friends
- You may ask the study doctor and site staff any questions**.**
- You may choose to not participate in this study, in which case you will not lose access to any medical care or other benefits already available to you.
- Take your time to decide.

Thank you for taking the time to consider this study. You can read more about Sisonke at: http://sisonkestudy.samrc.ac.za/

Why is this open-label study being conducted?

The J&J COVID-19 vaccine, Ad26.COV2.S, is being administered under study conditions while the regulatory processes are underway in South Africa. A single-dose regimen of this vaccine has been shown to be 64% effective overall in South Africa and 85% effective overall in preventing severe disease by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). This vaccine also demonstrated complete protection against COVID-19-related hospitalisation and deaths as from 28 days after receiving the vaccine.

Janssen Vaccine is filing for the emergency use of the single dose of the Ad26COV2.S vaccine in various regions of the world, including South Africa. This will happen within the next few months. This study is being conducted while these processes are ongoing in attempt to offer this vaccine as an emergency to health care workers. The vaccine will also be available once registered later in this year.

The vaccine, although protective against severe disease and hospitalisation in all regions of the world, was found to have less impact on other milder forms of disease because of new circulating virus variants, such as 501Y.V2 in South Africa. Because of this, we will be evaluating the effectiveness of the vaccine over the next 2 years.

You will receive a single injection of the Ad26.COV2.S vaccine as a participant in the study. There is no placebo.

General Information the COVID-19 vaccine

If you agree to participate in this open-label study you will receive a single injection of the vaccine and we will follow you up by reviewing your medical records and laboratory results for up to 2 years.

Already more than 43,000 participants around the world have participated in research to evaluate the safety and efficacy of this vaccine. A further 7 million have participated in the post licensure roll out of this vaccine.

You cannot get COVID-19 from the vaccine.

You may choose to not participate in this study, in which case you will not lose access to any other medical care or other benefits already available to you.

This study is funded by the SA MRC, the National Department of Health (NDoH) and the study sponsor is the SA MRC.

WHAT HAPPENS IN THIS OPEN LABEL STUDY?

The study is divided into 3 parts: 1) Scheduling your visits, 2) Vaccination Period, 3) Follow-Up Period.

WHO MAY PARTICIPATE?
You may participate if you are

- Age 18 and older
- Health care worker in the private or public service
- Willingness and ability to comply vaccination plan and other study procedures.
- Capable of giving electronic or personal signed informed consent which includes compliance with the requirements in this protocol.
- Pregnant women between 16 weeks and 34 weeks gestation who have a letter from their provider or antenatal care service
- Participants who report breastfeeding at the time of enrolment may be included

You may NOT participate

- if Any significant acute or chronic medical condition, situation or circumstance that in the opinion of the PI/designee makes you unsuitable for participation in the study, or jeopardises the safety or rights of the participant
- Participants who report being pregnant <16 weeks gestation at time of enrolment, planning conception within 3 months, or beyond 34 weeks gestation.
- Your current participation in any other research studies interferes with the objectives of this study. The determination of whether participation in another study would be exclusionary for a given participant will be made by the PI/designee.
- If you have a history of major venous and/or arterial thrombosis occurring with thrombocytopenia following vaccination with any COVID-19 vaccine.
- If you have previously been diagnosed with Heparin induced thrombocytopenic thrombosis.

Note well:

- Vaccination within 14-90 days with other COVID19 or non specific vaccines are not exclusionary but should be discussed with study PI or designee.

IT IS VERY IMPORTANT THAT IF YOU HAVE A PREVIOUS HISTORY OF SEVERE ALLERGY TO VACCINES OR HAVE A HISTORY OF SEVERE CLOTTING DISORDER THAT YOU LET THE SISONKE TEAM KNOW VIA THE NUMBER BELOW OR ASK TO LET THE RESEARCH SITE STAFF KNOW AT YOUR LOCAL VACCINE CENTRE PRIOR TO VACCINATION. THIS IS FOR YOUR OWN SAFETY.

This includes a history of cerebral venous sinus thrombosis (clotting in the brain), heparin-induced thrombocytopenia, or antiphospholipid syndrome (unusual blood disorders) or if you are on chronic anticoagulation medication, e.g. warfarin.

Some participants will have extra tests and procedures

If you have the above conditions, your enrolment will be discussed by the Sisonke safety team. If deemed to be suitable for enrolment and vaccination, you may need to do so under special precautions with more intensive follow up post vaccination. We will communicate this with you and assist you in this process.

Subgroup for special investigations:
There will be a sub-set of participants (approx 1000-1400) that will have extra tests and procedures.
If you volunteer to be part of the sub-group being followed up at 0,1,3 and 6 weeks and 6 months, we will collect a nasal swab to see if you have COVID-19 if you become symptomatic and blood samples (up to 60 ml or 12 teaspoons) at the time of vaccination, at 6 weeks and 6 months from you to evaluate your immune response to the vaccine. If you are breastfeeding a breastmilk sample (approximately 10mL) will also be taken at these time points.
We are also interested in exploring any clotting parameter abnormalities soon after vaccination. This will require a small amount of blood to be taken (10 mls) at weeks 0, 1 and 3.
Thus overall, you will attend at enrolment, 1,3 and 6 weeks and then 6 months and give 60mls of blood.

Pre-existing infections:
In a subset of 100 000 volunteer health care workers, we may obtain a sample of blood (1 teaspoon or 5ml) to check for pre-existing exposure to SARsCOV2 infection prior to vaccination. You may have had SARsCOV2 infection and been asymptomatic. This test will inform us of this.

STUDY RESPONSIBILITIES

To participate in the study, you have responsibilities.

Do

- Give correct information about your health history and health condition.
- Tell the study staff about any health problems you have.
- Report any side effects or health problems that may occur for 24 months post enrolment.

What is the Ad26.COV2.S study vaccine?

The Ad26.COV2.S study vaccine is made from a type of common cold virus called Adenovirus. The adenovirus used to make this vaccine is thought to be harmless to people because it has been weakened so it cannot replicate and cause a cold.

The Ad26.COV2.S study vaccine includes genetic material from the SARS-CoV-2 virus. When the study vaccine is injected into your body, the genetic material from SARS-CoV-2 gets "translated" to produce so called 'spike proteins' which are small bits of protein specific to SARS-CoV-2. Our bodies then make an immune response against these spike proteins. This immune response is our body's way of fighting the infection. You cannot contract COVID-19 from the study vaccine.

How is the vaccine given?

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.

You will remain at the study site for observation for about 15 minutes after receiving the vaccine.

There are currently no registered vaccines for COVID-19 in South Africa. There may be other studies in your area testing different vaccines against COVID-19.

WHAT ARE THE POSSIBLE SIDE EFFECTS AND RISKS OF PARTICIPATING?

Potential Discomforts, Side Effects, and Risks Associated with Ad26.COV2.S

Vaccines similar to Ad26.COV2.S (that is, Ad26-based vaccines) have been given to participants in studies designed to prevent RSV (Respiratory Syncytial Virus), HIV (Human Immunodeficiency Virus), Ebola/filovirus, Zika Virus, HPV (Human Papillomavirus) and malaria. As of 04 September 2020, Ad26-based vaccines have been administered to approximately 114,000 participants in ongoing and completed studies, including more than 99,000 participants in an ongoing Ebola vaccine study in the Democratic Republic of the Congo and in an ongoing immunization campaign in Rwanda. 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.

The Ad26.COV2.S has been studied in the test tube and in animals with no vaccine-related adverse effects observed. As of 2nd Feb 2021, a single injection of Ad26.COV2.S has been administered to at least 20,800 participants, aged 18 years and older. Following administration of Ad26.COV2.S, fever, muscle aches and headache appear to be more common in younger adults and can be severe. For this reason, we recommend you take a fever reducer or pain reliever such as paracetamol if symptoms appear after receiving the vaccination, or upon your study doctor's recommendation.

All vaccines can cause side effects. Problems that are not expected may happen and these may be important. If you have any side effects or problems during this study, please let the research site know immediately.

Risks and possible side effects of vaccines in general

All types of vaccinations can cause:

- Stinging, itching, arm discomfort, pain, soreness, redness, hardness, bruising and swelling where you receive the injection
- Fever
- Chills
- Rash
- Itching in other areas of your body
- Aches and pains
- Muscle and joint pain
- Throwing up and nausea
- Headache
- Dizziness
- Feeling very tired
- Fainting

These side effects usually last 2 to 3 days. So far, very few of these effects have been seen with this vaccine.

Rarely, people may have more severe side effects that limit their normal activities or make them go to the doctor. This occurred rarely with this vaccine in the phase 3 trial.

Allergic reactions

You could have an allergic reaction to a vaccine, including a rash, hives, or difficulty breathing. This is very rare. Some allergic reactions can be life-threatening. The study staff will watch you for at least 15 minutes after each injection. Always tell the study staff if you have ever had a bad reaction to any injection or vaccine. They may give you medicines in the clinic to treat serious allergic reactions. If you think you're having a severe allergic reaction after you leave the study site, contact the emergency number and get medical help right away. Let the research site know if this occurs.

IMPORTANT NEW INFORMATION: A rare clotting side effect

Most recently a very rare side effect has been reported in the USA in 6 people out of almost 7 million who have been vaccinated with the JnJ vaccine to date. Although not certain, it is thought this condition may be linked to vaccination through an immune phenomenon whereby auto-antibodies are formed against some of the parts of the blood system leading

to a tendency in the blood to make large clots. This results in the rare occurrence of the onset of clot formation with the simultaneous occurrence of low platelet numbers. The clots have mostly formed in the brain (central vein thrombosis), abdomen (splanchnic vein thrombosis), but also in other parts of the brain. In some cases there has also been bleeding resulting in some blood spots under the skin away from the injection site. This condition has now been called Vaccine Induced Thrombocytopenic Thrombosis, or VITT.

We can reassure participants who have received the JnJ vaccine as part of the Sisonke Phase 3b study in South Africa that we have not seen any cases of the formation of clots associated with low platelet counts among the almost 300 000 people who have received the vaccine as of end of Monday 12 April.

These very rare clotting events (1-4 cases in 1 million vaccinations) have occurred 4-20 days post vaccination with a median time of 8 days post vaccination. Most of the cases to date have included women under the age of 50 years with a mean age of 33 years.

If you develop any of the following symptoms, we advise that you seek care urgently, advise your doctor that you have recently been vaccinated and ask them to contact the Sisonke desk on 0800 014 956. **Symptoms that occur in this 4-28 day period should prompt you to seek care are:**

- new onset seizures; or weakness in a limb
- severe dizziness
- severe unrelenting blinding headaches with vomiting
- severe abdominal pain associated with vomiting
- blurred vision
- breathlessness
- pain in the chest or stomach
- swelling or coldness in a leg,
- after vaccination
- persistent bleeding
- multiple small bruises
- new leg pain reddish and/or purplish spots, or blood blisters under the skin

Your doctor, should this condition be suspected, is advised to make immediate contact with the Sisonke desk and **avoid heparin** until a diagnosis has been established. He may also urgently request a blood test to check your platelet count.

It is important to note that thromboembolic events are a common complication of COVID-19 infection. Clotting is also associated with other commonly used medications including certain types of contraception, with comorbidities such as obesity, diabetes and cardiovascular disease as well as smoking. These more typical events do not appear to be more commonly associated with this rare condition known as VITT.

Update on safety in Sisonke:

Thus far 2.2% of healthcare workers who received the JnJ vaccine as part of the Sisonke study reported side-effects or an adverse health event following vaccination. Only 134 people were referred for further evaluation at an emergency room or hospital. Most of these events have been minor, local or systemic reactions. One person experienced a severe allergic reaction that met the international diagnostic criteria for anaphylaxis but has since made a swift and complete recovery. We have noted some thromboembolic events (clotting events where the clot breaks off and travels to another part of the body to block a blood vessel) but none of these have been associated with the features described of a clinical syndrome of thrombosis in the presence of thrombocytopaenia (low platelet counts). The events reported internationally include cerebral venous sinus thrombosis with thrombocytopenia and in some cases widespread bleeding thought to be mediated through the creation of antibodies to platelet factor IV. These very rare events have also been reported following administration of other COVID-19 vaccines, eg AstraZeneca Vaccine.

There may be other risks associated with Ad26.COV2.S 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.

You will receive an SMS at the time of vaccination which will remind you to report any unusual symptoms or side effects and will link you to the online adverse events reporting system. Remember you can call the Sisonke desk at any time. You will also receive an SMS at 2 and 3 weeks post vaccination to remind you to let us know if you become ill at any time.

Risk of testing positive for SARS-CoV-2 antibodies

By receiving the Ad26.COV2.S vaccine, your 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 nose (or from your throat) as these tests tell you if you currently have COVID-19 virus in your body.
If you 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 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.

Other potential risks

Blood draws may cause pain, tenderness, bruising, bleeding, dizziness, vasovagal response, Syncope, and rarely, infection at the site where the blood is taken. Collection of a nasal swab sample may cause a nosebleed.

Benefits of Study Participation

You will receive access to an emergency use of this vaccine while we are awaiting regulatory approval. The single-dose Ad26.COV2.S vaccine regimen has been shown to be 64% effective overall in South Africa and 85% effective overall in preventing severe disease by

Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). This vaccine also demonstrated complete protection against COVID-19-related hospitalisation and deaths as from 28 days after receiving the vaccine.
You can choose to wait until the South African Health Products Regulatory Authority (SAHPRA) approves it for general use.

Participants may benefit from additional health information and clinical care.

COMMON QUESTIONS ABOUT JOINING THE STUDY

What are the costs of participating?
There are no costs to you to be in the study. The Sponsor and National Department of Health will supply the vaccine and the tests that are part of the study.

Can I change my mind about participating?
Yes. You can agree to be in the study now and change your mind at any time and for any reason. Your decision will not change any regular care that you receive from this clinic. Please talk to your study doctor before changing your mind about participation.

What if I get COVID-19 during the study?
You should contact the number below /on the vaccination cared if you have COVID disease. In addition, we will monitor hospitals in RSA for vaccinees who may become ill. If you are admitted or see a doctor, please inform them that you are on the Sisonke Study. If you are one of the subset of approximately 550-600 people who are having more intensive follow up, we will ask you at 6 weeks and 6 months what your experiences have been.

Can I take another vaccine after getting the Ad26 COVID-19 vaccine?
If you take another COVID-19 vaccine after receiving this one, please let your doctor know. We ask that you discuss with the study staff if you are considering receiving another COVID-19 vaccine. We recommend between 14 and 28 days between any vaccination depending on which it is- please discuss with your site staff or vaccinator.

What do I do if I have questions or problems?
If you have questions about this study or any problems that you think may be related to this study, contact the study staff during business hours at the Sisonke Desk at: **0800 014 956.**

BIRTH CONTROL PREGNANCY AND BREASTFEEDING DURING THE STUDY
Animal studies have shown that Janssen's licensed Ad26-based vaccine against Ebola did not raise concerns in preclinical reproductive toxicity studies. These are studies in pregnant animals that received the vaccine, and then delivered animal babies. Therefore, ongoing

studies with the Ebola vaccine allow pregnant women and women planning to become pregnant to receive that vaccine. While we understand more about this we would ask you about your pregnancy status at the vaccination visit.

If you are pregnant, you may be enrolled and vaccinated if

- You are between 16-34 weeks pregnant.
- You bring a letter of recommendation from your antenatal care provider to establish how many weeks pregnant you are and whether they support vaccination for you
- Sign an additional consent to vaccination at site

If you are pregnant or breastfeeding we urge you to report how you feel post vaccination through the adverse event link that will be sent to you via sms. When you complete this form please indicate that you are pregnant or breastfeeding (as applicable) when you complete this form.

If you suspect that you have become pregnant during the study, we ask you to notify the Sisonke Desk immediately. The Sisonke desk staff will collect information about your pregnancy and the health of your baby. If you do not wish to be followed, you can withdraw your consent at any time by informing your doctor.

What if something goes wrong for me?

If you become ill with COVID19 you will be referred to a COVID19 hospital for care. Please tell your treating doctor that you are enrolled in this study. Your treating doctor or you can contact the numbers below for more information.
Every care will be taken in the course of this study. However, in the unlikely event that you are injured by taking part, compensation may be available.

SAMRC insurance will provide compensation for reasonable medical expenses incurred as a result of study-related injury or illness, or death determined according to the guidelines laid down by the Association of the British Pharmaceutical Industry (ABPI Compensation Guidelines Version 2014), and Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa.
http://www.abpi.org.uk/media/1607/compensation_guidelines_2014.pdf

Please notify the investigator immediately of any complications, side effects and/or injuries during the study and the nature of the expenses to be covered.

If a research related injury occurs, you have not waived any of the legal rights which you otherwise would have as a participant in this study by signing this form.

The insurance does not cover medical treatment of other injuries or illnesses or injury caused by non-observance of the protocol.

The investigator is indemnified conditional on compliance with the protocol, SAHPRA and related research committees and is not a substitute for medical malpractice insurance.

Please note that if you have a life insurance policy you should enquire whether your insurance company requires notification of your intention to participate in a study like this. Information to date is that it should not affect any life insurance policy taken out. Nevertheless, you are strongly advised to clarify it with the company concerned.

REIMBURSEMENT

There is no cost or reimbursement for you to be in this study. However, you will receive access to an emergency use of the Ad26.COV2.S vaccine while we are awaiting regulatory approval.

EMERGENCY CARE AND HOSPITALISATION:

If you seek emergency care or if hospitalisation is required at any time during the study or up to 24 month/s after receiving this vaccine, please tell the treating doctor that you are/were enrolled in the Sisonke Study and that the Sisonke Safety Desk should be informed.

The number for the Sisonke Desk is: 0800 014 956.

ETHICAL APPROVAL

This clinical study protocol has been submitted to the South African Medical Research Council Ethics Committee and written approval has been granted by that Committee. The study has been structured in accordance with the Declaration of Helsinki (last updated: October 2013) which deals with the recommendations guiding doctors in biomedical research involving human participants. A copy may be obtained from me should you wish to review it.

If you have any additional questions about your rights as a research participant, you should contact the South African Medical Research Human Research Ethics Committee who is overseeing the conduct of this study at this clinical research centre. An Ethics Committee is an independent committee established to help protect the rights of research subjects.

Ms. Adri Labuschagne
SAMRC Ethics Committee
P.O. Box 19070
Tygerberg, Cape Town
Tel: 0219380687
Fax: 0866854023
E-mail: adri.labuschagne@mrc.ac.za

REGULATORY APPROVAL

If you have questions about this study you should first discuss them with the Sisonke Desk, the related site team or the related Ethics Committee. If you have not been provided with answers to your satisfaction, you should write to the South African Health Products Regulatory Authority (SAHPRA) who provides regulatory approval for the study at:

The Chief Executive Officer
South African Health Products Regulatory Authority
Department of Health
Private Bag X828
PRETORIA
0001
E-mail: Boitumelo.Semete@sahpra.org.za
Tel: (012) 501 0410

SAMPLES COLLECTED FOR SCIENTIFIC RESEARCH

What happens to the samples collected from me if I am in one of the smaller sub-set for more in-depth evaluation?

The Sponsor may use any of your samples collected during this study to

- Understand how the Ad26.COV2.S vaccine works, or why it may cause side effects
- To better understand COVID-19 disease
- To test if you may be infected with other respiratory viruses such as influenza (flu).
- Understand why people may respond differently to the study vaccine
- To better understand vaccines made from adenoviruses
- To develop tests for Ad26.COV2.S vaccine and SARS-CoV-2 infections.

To protect your privacy, your samples will be labelled with the study number and participant number. No personal identifiers are used (such as name, initials, social security number). The scientists doing the research will not know your identity.
Your samples may be sent to the Sponsor and other members of the Johnson & Johnson group of companies and to contractors working for them. Your samples may also be shared with other researchers. Your samples will not be sold or given to any other groups for their use. Researchers working with the Sponsor are not allowed to share samples with anyone who is not authorized by the Sponsor.
You will not be paid for any use of your samples or results, or for inventions made from research on them. You are providing your 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 collected samples will continue to be analysed as described in this form unless you specifically ask for your samples to be destroyed. This is to protect the quality of the study.

Samples Used for Future Research

Any samples remaining after they are used for the main study will be stored for future use for up to 15 years or as defined by local regulations. Testing will depend on the available technology at the time of testing. Additionally, your samples could be used for research on future COVID-19 vaccines or other respiratory viral disease vaccines.

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

The Study Staff and the Sponsor will manage your personal data (information about you) in compliance with South African regulations as described in this consent form.

What personal data will the study staff collect?

If you join this study, the study staff will collect and use your personal data that may include information about your health.

- Demographic information such as your name, your study ID #, home address, e-mail address, telephone/mobile number, date of birth, and gender which will be entered into the Vaccine Register
- Contact information about your emergency contact; and caregiver, if applicable
- The name of your regular doctor and the hospital where you would likely seek care if you become seriously ill with COVID-19
- Information about your physical or mental health or condition
- Information from any forms you are asked to complete

How will your personal data be protected?

All information obtained during the course of this study, including hospital records, personal data and research data will be kept strictly confidential. Data that may be reported in scientific journals will not include any information that identifies you as a participant in this study.

Any information uncovered regarding your test results or state of health as a result of your participation in this study will be held in strict confidence. You will be informed of any finding of importance to your health or continued participation in this study, but this information will not be disclosed to any third party in addition to the ones mentioned above without your written permission. The only exception to this rule will be cases of communicable diseases where a legal duty of notification of the Department of Health exists. In this case, you will be informed of our intent to disclose such information to the authorised state agency.

The Study Staff and the Sponsor will manage your personal data (information about you) in compliance with Protection of Personal Information (POPI) Act as described in this consent form.

How will Data be used by the Sponsor?

Your data is needed for the Sponsor to learn about Ad26.COV2.S, monitor its safety effectiveness. Therefore, they will be used as planned in this study as well as within related research activities in order to:

- understand how Ad26.COV2.S works in the body
- better understand COVID-19 and associated health problems
- develop diagnostic tests
- learn from past studies to plan new studies or improve scientific analysis methods
- publish research results in scientific journals or use them for educational purposes.

How will Your Coded Data be shared and transferred by the Sponsor?

The Sponsor may share Your Coded Data with its affiliates, health and regulatory authorities, ethics committees, 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 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 identity will not be revealed in any of these cases. These data will be utilised by them only in connection with carrying out their obligations relating to this clinical study. The Sponsor will protect Your Coded Data as far as the law allows and will keep and supervise the information collected about you only for as long as needed.

Sharing of your anonymized data by the Sponsor

Anonymized means your data and samples will be stripped of your 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 personal data be stored by the Sponsor?

Records containing your personal data will be retained at the study site for a period of 15 Years. In addition, the Sponsor will retain Your Coded Data for time periods as allowed per applicable laws for the identified use.

What rights do you have concerning your personal data?

If you would like to review, correct, delete, or make other requests about your personal data, you should contact your study doctor at [insert contact details].
You may not be able to review some of the data until after the end of the study and a request to delete your personal data cannot be fulfilled where regulations and laws that apply to clinical research require your personal data to be retained.
You can ask your study doctor to send any questions, concerns or complaints you may have to the Sponsor.

GENERAL STUDY INFORMATION

Who do I contact for information?

If you have any questions about the study, please contact:
Safety desk: 0800 014 956 or the Sisonke website at: http://sisonkestudy.samrc.ac.za/

If you feel that this study has caused you any harm, please contact:
Safety desk: 0800 014 956

If you have any questions about your rights as a research participant, please contact the study doctor/staff or:
SAMRC Human Research Ethics Committee on 0219380687

In addition, you may contact the
Sisonke Desk: **0800 014 956**

YOUR AGREEMENT TO PARTICIPATE

If you 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 Ad26.COV2.S experimental vaccine, and possible risks and benefits have been answered to my satisfaction.
- I give permission for my personal information to be collected from national and other laboratories as well as other approved data sources and kept in the Sponsor's database and understand that any data shared and used for the study as explained in this consent form will be Coded Data (anonymized).
- 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 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) about my participation in this study, and I agree to this. (You may still be in this study even if you do not agree to this.)

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

For the SUBSET participants only: I agree to the use of my samples for future scientific research as described in section "Samples Collected for Scientific Research".

Yes ☐ No ☐

Printed name and surname of participant in full

Signature of participant Date (dd/mmm/yyyy)

For participants who are unable to read or write, a witness should complete the signature block below:

Printed name and surname of witness in full

Signature of witness Date (dd/mmm/yyyy)

Printed name and surname of person obtaining consent

Signature of person obtaining consent Date (dd/mmm/yyyy)