INFORMED CONSENT FORM AND HIPAA AUTHORIZATION

TITLE: A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older

STUDY NAME: ENSEMBLE

PROTOCOL NO.: VAC31518COV3001
IRB Protocol # 20202387
14263

SPONSOR: Janssen Vaccines & Prevention B.V. (Janssen pharmaceutical company of Johnson & Johnson)

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You are invited to take part in this research study.

Here are a few 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.
- Our scientific question is: Does the study vaccine protect people from getting COVID-19 illness?
- If you join, your participation in this study will last for about 2 years.
- If you join, you will have injections, blood draws, saliva samples, and nasal swabs of your nose.

- Here are some risks of taking part:
    - The most common risks are symptoms are fever, muscle aches and headaches after getting the study vaccine.
    - There are other, less serious risks. We will tell you more about them later in this consent form.
- We do not know if getting the study vaccine will benefit you in any way.
- Take your time to decide. You may take an unsigned copy of this form home to re-read and discuss with your doctor/s, family, and friends.
- You 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 so you 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 healthcare provider(s), family and friends.

Why is this study being done?

This study is being done to test the new experimental vaccine called Ad26.COV2.S. Doctors and scientists hope it will prevent or lessen the severity of disease caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). This virus causes a disease called COVID-19. The SARS-CoV-2 virus 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 COVID-19 disease such as cough and extreme tiredness, but some people have severe disease and can even die.

The new experimental vaccine, called Ad26.COV2.S, may help to prevent disease by allowing the human body to form an immune response against the virus that causes the disease. This defensive response is a way your body fights infections. This study will help determine if Ad26.COV2.S is safe for humans and if it causes an immune response that protects against COVID-19 disease.

The main purposes of this study are to see:

- If the Ad26.COV2.S vaccine is safe
- To learn more about the side effects caused by the Ad26.COV2.S vaccine
- If the Ad26.COV2.S vaccine helps to prevent or lessen the severity of COVID-19 disease.

In this study, some participants will get a placebo instead of the Ad26.COV2.S vaccine. The placebo looks just like the Ad26.COV2.S vaccine and is given the same way, by injection (shot). But the placebo contains none of the study vaccines active ingredient(s). Using a placebo in the study allows researchers to see potential differences between the vaccine and the placebo. The placebo in this study will be sodium chloride, also known as saline (saltwater).

Throughout this document, when the words “study vaccine” are used, they can mean Ad26.COV2.S or placebo.

The U.S. Department of Health and Human Services declared a public health emergency due to COVID-19 pandemic on February 4, 2020 under a law called the Public Readiness and Emergency Preparedness Act, also known as the PREP Act. In response to the public health emergency, this Study is evaluating an investigational new vaccine called Ad26.COV2.S, to determine whether Ad26.COV2.S can safely and effectively be used to prevent SARS-CoV-2 mediated COVID-19. “Investigational” means that the study vaccine is currently being tested. It is not approved by the U.S. Food and Drug Administration (FDA).

General Information about the study
In total, 60,000 participants around the world will take part in this study.

If you join the study, you will be in it for about 2 years. During the study we will collect blood samples, saliva samples and nasal swabs. If you become sick with COVID-19 (and as explained later, you cannot get COVID-19 from the vaccine), the study staff will monitor you daily and request that you provide extra nasal swabs and saliva samples.

During the study, the Sponsor may learn new information about the study vaccine such as risks. Your study doctor will tell you as soon as possible about any new information that might make you change your mind about being in the study. It is possible that you will not benefit from participating in this study because we do not know if the vaccine works to prevent COVID-19 disease. There is a small chance you may have a bad reaction to the vaccine or that the vaccine may make you sicker if you do get COVID-19.

The study will be conducted in two stages for each age group. The first stage consists of 2000 participants aged 18-59 who do not have other health conditions. After they have received the injection of the study vaccine or placebo and have been observed for 3 days following the injection, all the remaining participants in that age group will be enrolled. The same process will be repeated for the group aged 60 and older. You will be informed which group you are in. If you do not qualify for the first group of participants, you may qualify for the second group of participants because of having other health conditions that place you at risk of progression to severe COVID-19.

Taking part in this study is your choice. You may choose to not participate in this study, in which case you will not lose any access to any medical care or other benefits to which you are otherwise entitled. There will not be any penalty if you decide not to take part.

This study is funded by Biomedical Advanced Research and Development Authority (BARDA) and the National Institute of Health (NIH), both of which are part of U.S. Department of Health and Human Services. Your study doctor will be paid by the sponsor.

WHAT HAPPENS DURING THE STUDY?
The study is divided into 3 parts: 1) Screening Period, 2) Main Study Period and 3) Follow-up Period.

Screening
Visit 1

- Screening is the process where it is determined whether you can participate.
- Screening happens before you receive the study injection.

Study Period
Visits 2-6

- The Main Study Period lasts about 1 year.
- You will receive the study injection on Visit 2 (Day1).
- You will use a secure app or a website called StudyHub to communicate with study staff and complete questionnaires.
- You will have up to 5 clinic visits during this period.
- If you develop COVID-10 symptoms, you will have additional visits. You may be asked to do some procedures at home.
- Some of the visits might be a telephone call or home visit by the study staff or home health care staff.
- If you stop the study early, you will be asked to complete an Early Exit visit.

Long-term Follow-up
Visits 7-8

- At the end of the Main Study Period, you will begin a 1-year follow-up period. The purpose of this period is to see how long the vaccine's protection might last.
- You will have up to 2 clinic visits during this period.
- If you develop COVID-19 symptoms, you will have additional visits. You may be asked to do some procedures at home.
- If you stop the study early, you will be asked to complete an Early Exit visit.

Some participants will have extra tests and procedures
There are two small groups of participants that will have extra tests and procedures: an Immuno Subset and a Safety Subset.

The Immuno Subset is a group of about 400 people who will have additional blood draws. The reason for this group is so researchers can take a closer look at their immune responses to the study vaccine.

The Safety Subset is a group of up to 6,000 people who are asked to complete additional diary questions after vaccination.

The study staff will tell you if you are included in either of these groups.

WHAT IS DONE AT THE STUDY VISITS?

Study procedures and activities
Throughout the study, you will have your height, weight, blood pressure, heart rate, and body temperature measured, and be asked to answer questions about your general health, medical history and the medications you take. You will be provided with an oral thermometer to measure body temperature, and an oximeter to measure pulse rate and the level of oxygen in your blood. In addition, if you are in the Safety Subset you will be provided with 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 video or phone call) or home visits by study staff or the company/agency supporting home health visits (if applicable).

Procedure	What is it?	When is it done?
Pulse oximetry	A small device called a pulse oximeter will be placed on your finger to measure the oxygen levels in your blood. The device can detect small changes in how efficiently oxygen is being carried through your body. This test is painless.	Visit 2 and as instructed if you experience COVID-19-like symptoms
Nasal Swab Testing	A cotton swab will be inserted in your nose and rotated to collect a sample of your nasal secretions. You may experience slight discomfort or tickling in the nose with this procedure. It may cause a nosebleed. A nasal swab kit will be given to you so that you can collect nasal samples at home if you develop COVID-19-like symptoms.	Visit 2 and as instructed if you experience COVID-19-like symptoms

	You will be trained by the site staff on how to use the nasal swab kit, how to store the collected sample (refrigerated), and when/how to return the collected sample to the study site (within 3 days after collection). The study site may arrange for supplies to be delivered to your home and for samples to be collected from your home. For this purpose, the study site may need to share your contact information with a courier.	
Saliva Sample Collection	A saliva sample kit will be given to you so that you can collect saliva samples at home if you develop COVID-19- like symptoms. You will be trained by the site staff on how to use the saliva sample kit, how to store the collected sample (at room temperature), and when/how to return the collected samples to the study site (within 3 days after collection). The study site may arrange for supplies to be delivered to your home and for samples to be collected from your home. For this purpose, the study site may need to share your contact information with a courier.	Visit 2 and as instructed if you experience COVID-19-like symptoms
Electronic Device Questionnaires	You will be asked to respond to questions about your health using an app on your smartphone or tablet or using a secure website (called Study Hub) on your computer. The study staff will provide you with a dedicated smart phone or tablet if you do not have one. Site staff will show you how to complete the questionnaires. It will take you a few minutes to complete most questionnaires. It may take about 15 minutes to complete questionnaires when you experience changes to your health. You may receive text messages as reminders to complete these questionnaires. You may have a caregiver or site staff assist with completion of questionnaires as needed.	During the Main Study Period, you will be asked to answer questions two times per week to monitor for new symptoms or health concerns that could be related to COVID-19. During the Follow Up Period, participants will be reminded to answer these questions two times per month.

	There are 3 types of questionnaires: - For all participants to monitor for any new symptoms or health concerns; - For those who develop symptoms of COVID-19 to provide information about the signs and symptoms they experience (including measuring body temperature, pulse oximetry and heart rate); - For those in the Safety Subset to report reactions after vaccination (including measuring body temperature and measuring any redness and/or swelling where they received the vaccine).	If you develop signs and symptoms of COVID-19, you are asked to report this immediately via the application. In addition, you will be asked to respond daily to questions about the symptoms you have. In addition, participants in **Safety Subset** will report reactions after vaccination. This will be done on a daily basis for 8 days starting from the day of vaccination.

Procedure	**What is it?**	**When is it done?**
Blood draw/tests	The study doctor or staff will draw blood from a vein in your arm. You may have pain, get a bruise or irritation at the place where the needle goes into your skin. Some participants may faint. In rare cases, the blood draw can cause an infection. The total amount of blood that will be drawn during the entire study is 52.5 mL (about 4 Tablespoons). The total amount of blood that will be drawn from participants in the Immuno Subset will be 107.5mL (about 8 Tablespoons). An additional 35 mL (about 2.5 Tablespoons) should you develop COVID-19 disease. • For most participants, the total amount of blood drawn during the study will be about 52.5 mL (about 4 Tablespoons).	All participants will have blood drawn at Visit 2, 3, 4, 5, 6 or at Early Exit visit. Participants in the Immuno Subset will have additional blood draws at Visits 7 and 8. Additional amount will be drawn from participants who develop COVID-19 disease. Sometimes you may need to repeat a blood test.

	• Participants in the Immuno Subset will have additional 55 mL (about 4 Tablespoons) blood drawn during the study to check for immune responses. • An additional 35 mL (about 2.5 Tablespoons) will be drawn from participants who develop COVID-19 disease. You may be asked to repeat a blood test if there are safety or technical issues with the initial draw. Your blood will be used to check • For confirmation of SARS-CoV-2 infection • Your immune response to the study vaccine Positive tests will be reported to applicable health authorities.	
Urine sample	If you are a female who could get pregnant, we will collect a urine sample from you to check for pregnancy.	Visit 1, Visit 2
Sample collection for scientific/genetic research	Any of your blood samples could be used for scientific and limited genetic research as described in the "Samples Collected for Scientific/Genetic Research" section below. You will be informed if testing on your samples for this study changes.	

If Home Health Care Visits Will Occur (your study doctor will let you know if this section applies to you)

Your study doctor will provide the company/agency supporting home health visits with your contact details (name, email, address, telephone number). The company/agency supporting home health visits will then share your information with the assigned medical professional who will perform the study visit. The medical professional will contact you to schedule the visit. The medical professional will arrive at your preferred location and will perform the procedures and capture any visit data within the company/agency supporting home health visit's Home Healthcare System. The medical professional might also request information regarding your current and past health issues. This data will be transferred to your study site via the company/agency supporting home health visit's Home Healthcare System available for your study staff to view and use per study

requirements. Your study doctor will review the visit data and may request that you visit the study site for a follow-up visit if needed.

You have the right to cancel a Home Health Care visit at any time. You also have the right to opt out of Home Health Care visits at any time. Your participation in this trial is not dependent on your acceptance of a Home Health Care visit. If you decide to cancel a Home Health Care visit, please notify your study doctor so that the visit can be rescheduled as needed. Your decision to opt in or opt out of Home Health Care visits will not affect your regular study participation.

StudyHub
A secure online platform called StudyHub will be used in this study. The Sponsor is working with IQVIA (a clinical research organization) to use StudyHub to support this study. StudyHub is the place for you to communicate with study staff, complete study tasks and find important information about the study. You will access StudyHub using a secure app on your smartphone or tablet or by using a secure website you can access through any computer.

To access StudyHub, you will need to set up an account. If you choose to use the application on a smartphone or tablet, your study team will assist you in the set-up and you will receive notifications through e-mail at first. Once your account has been set up, you can change your notification preferences in the app settings. If you choose to use StudyHub on a web browser, you will receive account setup and instructions and study notifications via e-mail. You can also choose to receive text messaging/SMS notifications. You can turn this off at any time by replying STOP.

There is a service called the “Study Concierge” that is accessible to you 24 hours/day, 7 days/week if you have questions or need technical assistance with StudyHub. The Study Concierge is a centralized support managed by IQVIA on behalf of your study site staff. You can reach the Study Concierge through StudyHub. However, all medical questions should be directed to your study site staff.

Some of the study procedures may be done through StudyHub. If the study staff conducts a telemedicine visit, they will use the secure connections and the camera on your device so that you can see each other during the call. The study staff can tell you more about this.

STUDY RESPONSIBILITIES
To participate in the study, you have responsibilities.

Overall	
Do	**Do not**
• Give correct information about your health history and health condition. • Tell the study staff about any health problems you have during the study. Note: you should contact the study staff as soon as you start experiencing COVID-19 symptoms. • Talk to your study doctor before getting any other licensed vaccines (such as flu vaccine). • Tell the study staff about any new medicine or drug you 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 ongoing medicines or drugs. • Complete the electronic questionnaires as directed. • Provide all required samples, e.g. nasal swabs, saliva 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 bone marrow, 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 Ad26.COV2.S 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 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.

Ad26.COV2.S is “investigational”, which means it is not approved for use by the United States Food and Drug Administration (FDA) or any Regulatory Authority in any country. Therefore, it can only be used in a research study such as this one.

What injection will I receive?
Not everyone in the study will receive Ad26.COV2.S. You will either get injected with Ad26.COV2.S or with a placebo. The placebo looks just like the study vaccine and is given the same way (by injection) but has no active ingredient(s) in it. The placebo in this study will be sterile saltwater.

A computer will randomly assign you to either group by chance, like flipping a coin. You will have a 50% chance of being put in either group:

- Group 1 – Ad26.COV2.S
- Group 2 – Placebo

During the study, neither you nor the study staff will know which group you're 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 upper arm. When possible, the injection will be given in the arm you use less. This will be done at Visit 2 (Day 1).

You will remain at the study site for observation for at least 15 minutes after receiving the vaccine. The first 2000 recipients will remain at the study site for observation for at least 30 minutes after receiving the vaccine.

What other options are there besides this study?
You do not have to take part in this study. There are currently no approved vaccines for COVID-19. There may be other studies in your area testing different vaccines against COVID-19. Your study doctor will discuss these options, and their risks and benefits, with you.

What about my current medicines?
The study staff will ask about all prescription and over-the-counter medicines that you are taking. This includes vitamins and herbs. The study staff will let you know if there are medications you 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 Ad26.COV2.S
The Ad26.COV2.S has been studied in the test tube and in animals with no vaccine-related adverse effects observed.

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.

As of 10 September 2020, a single injection of Ad26.COV2.S has been administered to 805 human participants, aged 18 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 if symptoms appear after receiving the vaccination, or upon your study doctor's recommendation. Please tell the study staff if you take anything.

Some vaccines may cause a more severe course of disease when you are vaccinated against a disease and then become infected by that disease germ. This is called vaccine-enhanced disease and it has been described during animal testing for some vaccines against other coronavirus infections such as SARS (Severe Acute Respiratory Syndrome) and MERS (Middle East Respiratory Syndrome). However, studies in human volunteers with vaccines using similar technology to Ad26.COV2.S have produced responses that are not associated with vaccine-enhanced disease. Nevertheless, the risk of a more severe course of SARS-CoV-2 infection cannot be absolutely ruled out with the vaccine tested in this study. Because of this, all participants in this study will be monitored for vaccine-enhanced disease throughout the study. We will do this by taking nasal swabs in participants suspected of having SARS-CoV-2 infection. Study participants with a positive test result will be followed until the sign and symptoms have been resolved. These procedures will allow us to recognize and intervene early in the course of disease. Early recognition and intervention will reduce the risk of a bad outcome if enhanced disease, should it occur.

All vaccines can cause side effects. Problems that are not expected may happen and these may be life-threatening. If you have any side effects or problems during this study, please tell your study doctor right away.

There may be 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.

Risks and possible side effects of vaccines in general
All types of injections 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.

Rarely, people may have more severe side effects that limit their normal activities or make them go to the doctor.

Allergic reactions
You could have an allergic reaction to a vaccine, including a rash, hives, sudden change in blood pressure (making you feel dizzy or lightheaded), fast pulse, sweating, or difficulty breathing. **Some allergic reactions can be life-threatening**. The study staff will watch you for at least 15 minutes after your injection.

Always tell the study staff if you have ever had a bad reaction to any injection or vaccine. They can 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.

Risk of testing positive for SARS-CoV-2 antibodies
If you receive the AD26.COV2.S vaccine (instead of placebo), 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. Some tests, however, are done to check if you have previously been infected with COVID-19—these tests check for antibodies. These antibody test results might be positive if you received the AD26.COV2.S vaccine, even if you were never

truly infected with the virus. For this reason, we recommend that you not seek testing outside of this study, but rather speak with study staff if you need to get tested. The study staff will provide you with additional information and help you get the right test.

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. We do not know the effect of the study vaccine on babies before they are born, or on nursing children.

Other potential risks:

Confidentiality
Because information for this study will be obtained using StudyHub on the internet, there is some risk of disclosure of your personal information. All efforts will be made to protect your information, however not all internet connections are secure.

If you use your mobile device for StudyHub, it is highly recommended that you set up a passcode on your own phone/device to help prevent unauthorized access to your phone and research data.

COMMON QUESTIONS ABOUT JOINING THE STUDY

Will I be paid?
Payments will be based on the number of visits you complete and whether these visits take place at the site or at your home.

Visit		Subject Stipend
Visit 1		$150
Visit 2		$105
Visit 1/Visit 2		$235
Visit 3	Site	$140
	Home	$90
Visit 4	Site	$101
	Home	$25
Visit 5	Site	$190
	Home	$140
Visit 6	Site	$230
	Home	$180
Visit 7	Site	$130
	Home	$80

Visit		Subject Stipend
Visit 8	Site	$101
	Home	$50
Early Exit	Site	$101
	Home	$20
Telehealth Visit		$20

COVID-19 Signs & Symptoms Visits		Subject Stipend
Day 1-2		$20
Days 3-5 Part 1	Site	$101
	Home	$20
Days 3-5 Part 2	Site	$101
	Home	$20
Cycle Day 1		$20
Cycle Day 2		$20
Day 29	Site	$101
	Home	$20

You will receive payment via a ClinCard, which is a specially designed debit card for clinical research that works like a bank debit card. Each time you receive a payment for participation in this study, the money will be added to the card after each completed visit. The debit card system is administered by an outside company. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. In order to receive payment, we will need to collect some information about you, including your name, address, date of birth, medical record number, social security number, and your patient study ID code. All information is stored in a secure fashion and will be deleted from our records once the study has been completed and the funds on your ClinCard have been exhausted.

You may use this card at any store that accepts credit cards. You may also withdraw cash. Please be aware that there may be fees drawn against the balance of the card for cash withdrawals and inactivity. You will receive additional information on how you can use this card and any fees that may apply.

If you receive $600 or more for taking part in this research study or a combination of studies in one tax year, you will be sent a 1099 form for tax purposes.

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

The Sponsor will not pay for doctor visits, treatments, or tests that are not part of this study. This includes visits/hospitalizations for COVID-19.

This means that you, your insurance company, or your government health plan are responsible for paying for routine care you would receive whether or not you are in the study. You may talk to the study staff and your insurance company about what is covered.

Can the study staff remove me from the study?
Yes, the study staff and the Sponsor have the right to remove you from the study at any time without your consent. This decision may occur if:

- It is in your best medical interest to do so
- You do not follow the study staff's instructions
- The study is canceled by the FDA or the sponsor
- You are no longer following the study requirements

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

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**.

There will not be any penalty or loss of benefits to which you are otherwise entitled if you leave the study early. 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. If you decide to leave the study early, there may be risks with this decision. You should discuss these risks with your study doctor. You may be asked to return to the clinic for tests.

What if I get COVID-19 during the study?
When you enroll into the study, you will be asked to provide the name of your regular doctor and the hospital you would likely seek care at if you become seriously ill. This is so we can be sure to follow you to check your health. You should contact the study staff as soon as you start experiencing COVID-19-like symptoms. Study staff will monitor your health and may visit you in your home. If you seek health care for COVID-19 by a nurse or doctor at a clinic, Emergency Department, or hospital, we ask that you bring a form with you to present. The study staff will give you this form at the start of the study and provide you instructions on what to do with it. It is important that you keep this form in a safe place while you are participating in the study. If you turn out to be positive for COVID-19, local guidelines will mandate 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 stop the study early, the study staff will ask you to do an Early Exit visit. This is to check your health. This information will be added to your study record. If you do not want the study doctor to continue monitoring your health after you stop taking the study vaccine, you will be asked to indicate this by informing the study doctor. However, it is recommended that you continue to have the study doctor follow you for safety for a period of time.

If the study staff is unable to contact you by conventional means (e.g., clinic/practice visit, telephone, e-mail, fax, or certified mail), he/she may also contact you by reaching out to your emergency contact or by locator agencies and public records, as permitted by local regulations to find out about your health status. By signing this consent form, you agree that this information can be obtained and added to your study record.

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

If you stop the study early and withdraw your consent at any time, you agree to allow the use of information collected about you for the purpose of the study up to the point of your consent withdrawal. The Sponsor will continue to collect information from you as described in other sections of this Informed Consent Form (see “Samples Collected for Scientific/Genetic Research,” “Samples Used for Future Research,” and “What happens if I stop the study early?”). The Sponsor will not collect any new information from you for any parts of the study from which you have withdrawn unless you have a side effect related to the study.

Can I take the study vaccine after the study is over?
After you complete the trial, you will no longer receive Ad26.COV2.S. If you received the placebo, you may be offered the study vaccine at no cost if and when the study vaccine has been shown to be safe and that it works, but it is possible that this may not occur until 2 years after vaccination. This will be determined after consultation with the national health authorities in your country.

What are the benefits of joining this study?
If you receive the study vaccine, your body may or may not produce an immune response that protects you against COVID-19. There may be no direct medical benefit to you for participation in this clinical study. Your participation, however, will provide information about the study vaccine and may help future patients.

WHAT IF SOMETHING GOES WRONG?
You will not be responsible for costs of your medical injuries related to your participation in this study, as long as the injury is not part of the natural progression of your disease

or your carelessness. We may need to know some information (like name, date of birth, Medicare insurance, claim number and/or social security number) to pay these medical expenses. In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Medical services will be offered at the usual charge. However, compensation for things such as lost wages, disability or discomfort is not routinely available.

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

Signing this form does not waive your legal rights nor does it relieve the investigators, the Sponsor, or the involved institutions from their legal and professional responsibilities. However, during this public health emergency, you should be aware that the PREP Act may provide immunity (meaning protection from being sued) for the Sponsor, Study Doctor, and others involved in this Study from liability.

If the Sponsor provides compensation for injury, it is not waiving immunity provided under the PREP Act.

As part of the public health emergency declared by the Department of Health and Human Services a national fund called the Countermeasures Injury Compensation Program (CICP) may be established for purposes of providing compensation to eligible individuals for serious physical injury or death directly caused by the administration or use of a treatment that is a countermeasure under the PREP Act. If funds are appropriated by Congress, compensation for injuries may be available to you under this Countermeasures Injury Compensation Program. However, there is no guarantee that funds will be provided by Congress for that purpose. You may find information about the CICP at https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427.

BIRTH CONTROL AND PREGNANCY 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 normal animal babies. Therefore, ongoing studies with the Ebola vaccine allow pregnant women and women planning to become pregnant to receive that vaccine. However, these studies are not yet available for Ad26.COV2.S. For this reason, in this study, we will not enroll pregnant women, or those who aim to get pregnant within 3 months of receiving the study vaccine. The appropriate animal studies are currently underway.

Female Participants Who Cannot Get Pregnant:

If you are postmenopausal for at least two years or have had a total hysterectomy (surgical removal of the womb) or bilateral tubal ligation/clip (surgical sterilization) or surgical removal of both ovaries, you cannot get pregnant. Therefore, the section about contraceptive use does not apply to you.

Female Participants Who Can Get Pregnant:
If you are female and can get pregnant (meaning that you are neither post-menopausal for two years nor surgically sterile) and sexually active, you must avoid getting pregnant in order to take part in this study. You 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 will need to have a negative pregnancy test before vaccination.

Birth control methods that can be used while in this study include:

- Hormonal contraception
- Intrauterine devices (IUD)
- Intrauterine hormone-releasing systems
- Vasectomized partner (the vasectomized partner should be your sole partner)
- Abstinence (defined as refraining from heterosexual intercourse from signing the informed consent until at least 3 months following the last study vaccination)

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

If you are a female who can get pregnant, you must agree to have a urine β-hCG pregnancy test at screening and immediately prior to the study vaccine administration to demonstrate that you are not pregnant.

If you suspect that you have become pregnant during the study, you must notify your study doctor immediately. If you become pregnant during the study, you may continue in other study procedures (you may have blood drawn for safety and immune response testing), if the investigator decides it is safe for you and your unborn child. The study doctor 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.

Male Participants Whose Partner Can Get Pregnant:
If your partner becomes pregnant during the study, you should tell the study doctor immediately. Your 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 partner does not have to provide any information.

SAMPLES COLLECTED FOR SCIENTIFIC/GENETIC RESEARCH

What happens to the samples collected from me?
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.

Researchers may use your samples for genetic testing. Genetic research is the study of DNA (Deoxyribonucleic acid) and RNA (Ribonucleic acid). Differences in genes may explain why some people respond to some medications and others do not. It may also explain why some people get some diseases and others do not.

The results of genetic tests done on your samples are only for use in scientific research. They will not be used for your medical care or to make a diagnosis about your health. Therefore, these results will not be given to you or the study staff.

To protect your privacy, your 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 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 analyzed 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. 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 Sponsor plans to keep the samples securely in CSM Biomedical Sample Management Inc. in the USA. The samples may be relocated at any time by the Sponsor.

HOW IS MY PRIVACY PROTECTED?
The Study Staff and the Sponsor will manage your personal data (information about you) in compliance with the Health Insurance Portability and Accountability Act (HIPAA) as described in this consent form. Federal regulations give you certain rights related to your health information. These include the right to know who will receive the information and how it will be used. The study doctor must obtain your authorization (permission) to use or release any health information that might identify you.

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.

The study staff will also collect, record, and use personal information about you, for study purposes only, within StudyHub, which is a secure internet portal. Your personal information collected in StudyHub may include:

- 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 StudyHub to create your account;
- 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
- Sensitive information about your physical or mental health or condition
- Medical records (from any doctor, hospital or other healthcare provider)
- Information from the questionnaires you are asked to complete

- Information created or collected during the research. This could include your medical history, and dates or results from any physical exams, laboratory tests or other tests.

The site will use some of your demographic information to create your account in StudyHub and help you download the StudyHub application to your device when you enroll. You will also be able to manage and update your user profile and adjust preferences about communications. All information which is collected about you in StudyHub that is exported 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 subject number. Only the study doctor and the study team (including the IQVIA study concierge on behalf of the study team) will have access to information that can link you to your subject number; this information will not be shared outside of the StudyHub portal unless necessary for safety purposes.

If you agree, we will collect information regarding your current work, your living/housing situation, and your social interactions. The purpose of this is to see if we can identify work, living or social situations that are associated with COVID-19 disease. You are not obligated to share this information: you can accept or refuse to provide this information.

How will your personal data be protected in StudyHub?
Your records will be kept secure during this process.

Your study doctor can provide you with more information about the StudyHub and data collected.

When becoming a Study Hub user, you will be presented the End User License Agreement and Privacy Policy linked to Study Hub, where you can find more details on the use of the platform and how the data collected is used, handled and protected.

Once all your study activities have been completed or you have withdrawn from the study, you can remove the StudyHub application from your phone by following your device's standard procedures for removing applications. You can contact the StudyHub team if you need assistance with this.

After all participants have completed the study, the StudyHub application will be deactivated.

How will your personal data be protected for Home Health Care? (your study doctor will let you know if this section applies to you)
The company/agency supporting home health visits and their courier will manage your personal data (information about you) in compliance as outlined in main consent. The original consent form you signed, remains valid also for Home Health Care, with the exception that your contact details will be disclosed and processed by the

company/agency supporting home health visits and their courier and the assigned medical professional as required for the performance of Home Health Care services as described in this form.

The company/agency supporting home health visits and their courier will maintain the confidentiality of any personal information and medical data collected by storing it in a secure system. Your study staff will have access to this system in order to review the data and for inclusion in your study file.

Who else will have access to your personal data?
Your personal data will be labeled with the study number and your subject number ("Your Coded Data") before it is reported to the Sponsor. No direct personal identifiers such as your name, initials, date of birth, or social security number are included in Your Coded Data. Your personal data may be stored in paper files and electronic databases which have limited access. The study staff will have access to them. Other people may also need access to this information to ensure that the research study is being conducted properly, in accordance with laws and ethical requirements.

The study doctor and study staff will share your personal health information with:

- The study Sponsor, people who work with the sponsor on the study,
- monitor(s),
- auditor(s),
- the Institutional Review Board (IRB) that reviewed this research. The IRB is a group of scientists and non-scientists who review the ethics of research. The goal of the IRB is to protect the rights and welfare of study subjects,
- regulatory authorities such as the FDA,
- Department of Health and Human Services (DHHS) agencies,
- other regulatory agencies

You should also know that the Henry Ford Health System Institutional Review Board (IRB) and IRB Administration Office may inspect study records as part of its auditing program, but these reviews only focus on the researchers. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

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

Records identifying you 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 identity will remain confidential.

Some of this information, called Protected Health Information ("PHI"), is protected by federal privacy laws. By signing this consent form, you give your permission to have your PHI collected, used and disclosed for purposes of this study. After the Study staff or the Study doctor discloses your PHI to others, it could be re-disclosed and no longer protected by federal privacy laws.

You may decide not to give permission for the use or disclosure of your protected health information for the study. In that case, you 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. Your decision not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are otherwise entitled.

Remote access to your records at the study site
Representatives of the Sponsor (i.e., auditors) may use an electronic tool to access your personal 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 Coded Data be used by the Sponsor?
Your Coded Data is needed for the Sponsor to learn about Ad26.COV2.S, get permission to introduce and keep it on the market, monitor its safety and get it covered by health insurances and health service providers. 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, regulatory authorities (such as the FDA), the IRB, 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.

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 at least 2 years after the last approval of a marketing application or after the formal discontinuation of clinical development of the investigational product. 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 the phone number(s) listed above on the first page.

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.

Protections for Genetic Information A Federal law, called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.
- All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

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

- If you no longer want to share your protected health information, you may cancel your 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 cancel your permission after you have started in the study, the study staff and the Study doctor will stop collecting your health information unless you have a side effect related to the study. Although they will stop collecting new information about you, they will need to use and share the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you 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 participation, or if you decide not to continue, you 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 withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends.
- Your decision to withdraw your Authorization will not involve any penalty or loss of access to treatment or other benefits to which you are otherwise entitled.

If you do not withdraw this Authorization, it will remain in effect.

If the research site is located in California, Delaware, Indiana, Washington, or Wisconsin this authorization will expire on 31Dec2070.

There is no expiration of this authorization except for research conducted in the states listed above.

HOW DO I LEARN ABOUT THE STUDY RESULTS?

The Sponsor will analyze the data and offer you a summary of the study results after all study participants have completed the study. This may be some time after you have completed your 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 a written summary.

GENERAL STUDY INFORMATION

Who do I contact for information?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number(s) listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (888)-303-2224 or (800) 562-4789, irb@cgirb.com if:

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

OR

You may also contact the Henry Ford Health System IRB Administration Office by phone at (313) 874-4464 or by email at research_admin@hfhs.org.

Study information

Study title: A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older

Study number: VAC31518COV3001
Study name: ENSEMBLE

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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 and kept in StudyHub 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) 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.) (Please mark your choice below.)

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

I give permission for the study staff to inform my designated doctor of any positive SARS-COV2 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 use of my samples for future scientific research as described in section “Samples Collected for Scientific/Genetic Research”. (Please mark your choice below.)

Yes	No
☐	☐

I agree to respond to questions regarding my work, home and social situation as described in section “What personal data will the study staff collect?”.

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 company/agency supporting home health visits and as applicable, their courier, will be provided with my name, address and phone number and will contact me to schedule a Home Health Care visit. (You may still be in this study even if you do not agree to this.)

(Your study doctor will let you know if this applies to you.) (Please mark your choice below.)

Yes ☐ No ☐

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

Printed name of participant in full

Signature of participant — Date (dd/MON/yyyy) - Time

Printed name of person obtaining consent

Signature of person obtaining consent — Date (dd/MON/yyyy) - Time

Printed name of investigator if different from the person obtaining consent

Signature of investigator if different from the person obtaining consent — Date (dd/MON/yyyy) - Time