



# COVID-19 VACCINE INFORMATION AND CONSENT FORM

1<sup>st</sup> Dose       2<sup>nd</sup> Dose

<b>Name:</b> _____ First                                  Middle                                  Last				
<b>Address:</b> _____ Street    City                                  State                                  Zip				
<b>Telephone:</b> (____) _____ -- _____			Covered by Insurance, Medicaid, or Medicare: <input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>Date of Birth:</b> ____ -- ____ -- ____	<b>Age:</b> _____	<b>Gender:</b> <input type="checkbox"/> Male <input type="checkbox"/> Female	<b>Primary Language:</b> <input type="checkbox"/> English <input type="checkbox"/> Other	<b>Ethnicity: (check only 1)</b> <input type="checkbox"/> Not Hispanic <input type="checkbox"/> Hispanic <input type="checkbox"/> Unknown
<b>Race: (check only 1)</b> <input type="checkbox"/> Asian/Polynesian <input type="checkbox"/> Black <input type="checkbox"/> White <input type="checkbox"/> Multiracial <input type="checkbox"/> Native Am/Alaskan <input type="checkbox"/> Unknown			<b>Emergency Contact Phone#:</b> <b>Name:</b> _____	

Please answer the health questions below:	Yes	No	Unknown
1. Are you sick today or currently in an isolation or quarantine period for COVID-19?			
2. Have you had a positive COVID-19 test in the last 3 months/90 days?			
3. Have you received passive antibody therapy as treatment for COVID-19?			
4. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something? For example, a reaction for which you were treated with epinephrine or EpiPen®, or for which you had to go to the hospital?			
5. Have you ever had a serious reaction after receiving a vaccine or another injectable medication?			
6. Have you received any vaccinations in the past two weeks/14 days?			
7. Do you have a bleeding disorder or are you taking a blood thinner?			
8. Do you currently have a weakened immune system, take immunosuppressive medications, or receive radiation or chemotherapy treatment?			
9. Are you pregnant or currently breastfeeding?			
10. Have you ever received a dose of COVID-19 vaccine? If yes, which vaccine? <input type="checkbox"/> Moderna <input type="checkbox"/> Pfizer <input type="checkbox"/> Other: _____ Date received: _____			

- I have been given a copy and have read, or have had explained to me, the information in the **FACT SHEET** for the COVID-19 vaccine I will receive. I understand the FDA has authorized emergency use of the COVID-19 vaccine, which is not an FDA-approved vaccine. I have had the chance to ask questions that were answered to my satisfaction.
- **I understand Moderna & Pfizer COVID-19 vaccines require 2 doses.** If this is my first dose of either of these COVID-19 vaccines, I intend to receive a second dose of the same vaccine in accordance with the timeframe specified in the FACT SHEET to complete the vaccination series. **Janssen** vaccine is a single dose vaccine.
- **My signature acknowledges that I was advised to remain on site for 15 minutes after receiving the vaccine. Those with a history of previous anaphylactic reactions, should stay on site for 30 minutes.** I understand that if I experience any adverse reaction, it will be my responsibility to follow up with my primary care physician.
- An administration fee may be billed to third-party payers. I authorize the Southeast Health District to bill any and all third-party payers for this service. I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits or payment of medical benefits either to myself or to the party who accepts assignment for services described herein.
- I understand the significant known and potential risks and benefits of the COVID-19 vaccine as explained in the FACT SHEET and that some potential risks and benefits may remain unknown. **I REQUEST THE COVID-19 VACCINE BE GIVEN TO ME OR THE PERSON LISTED ABOVE.**

\_\_\_\_\_ X \_\_\_\_\_  
 Date                                  Print Name                                  Patient or Parent/Guardian Signature

OFFICE USE ONLY		Record of Immunization				OFFICE USE ONLY	
Vaccine	Lot #	Exp Date	Dose	Route – Site	DATE	Provider Signature, Title	
MOD JANSSEN			0.5 ml	<input type="checkbox"/> IM <b>LEFT</b> Deltoid <input type="checkbox"/> IM <b>RIGHT</b> Deltoid			



**Get vaccinated.  
Get your smartphone.  
Get started with v-safe.**

## ***What is v-safe?***

**V-safe** is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through **v-safe**, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And **v-safe** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's **v-safe** makes a difference—it helps keep COVID-19 vaccines safe.

## ***How can I participate?***

Once you get a COVID-19 vaccine, you can enroll in **v-safe** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from **v-safe** around 2 p.m. local time. To opt out, simply text "STOP" when **v-safe** sends you a text message. You can also start **v-safe** again by texting "START."

## ***How long do v-safe check-ins last?***

During the first week after you get your vaccine, **v-safe** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions **v-safe** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, **v-safe** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

## ***Is my health information safe?***

Yes. Your personal information in **v-safe** is protected so that it stays confidential and private.\*



Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.



Sign up with your smartphone's browser at [vsafe.cdc.gov](https://vsafe.cdc.gov)

**OR**

Aim your smartphone's camera at this code



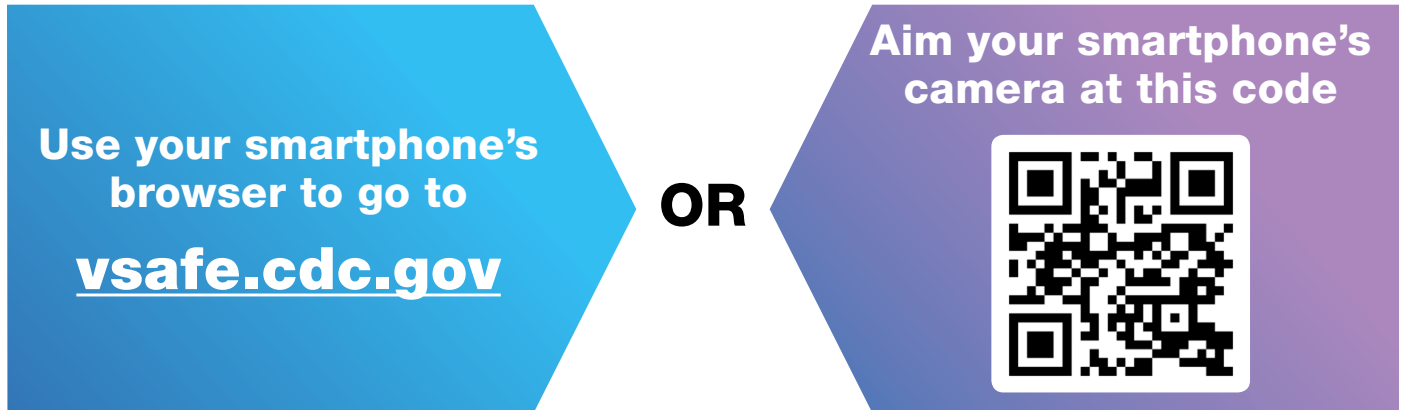
\*To the extent **v-safe** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity.

## How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

### Register

1. Go to the **v-safe** website using one of the two options below:



2. Read the instructions. Click **Get Started**.
3. Enter your name, mobile number, and other requested information. Click **Register**.
4. You will receive a text message with a verification code on your smartphone. Enter the code in **v-safe** and click **Verify**.
5. At the top of the screen, click **Enter vaccine information**.
6. Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click **Next**.
7. Review your vaccine information. If correct, click **Submit**. If not, click **Go Back**.
8. **Congrats! You're all set!** If you complete your registration before 2 p.m. local time, **v-safe** will start your initial health check-in around 2 p.m. that day. If you register after 2 p.m., **v-safe** will start your initial health check-in immediately after you register—just follow the instructions. You will receive a reminder text message from v-safe when it's time for the next check-in — around 2 p.m. local time. Just click the link in the text message to start the check-in.

### Complete a v-safe health check-in

1. When you receive a **v-safe** check-in text message on your smartphone, click the link when ready.
2. Follow the instructions to complete the check-in.

### Troubleshooting

#### How can I come back and finish a check-in later if I'm interrupted?

- Click the link in the text message reminder to restart and complete your check-in.

#### How do I update my vaccine information after my second COVID-19 vaccine dose?

- **V-safe** will automatically ask you to update your second dose information. Just follow the instructions.

#### Need help with v-safe?

Call 800-CDC-INFO (800-232-4636)

TTY 888-232-6348

Open 24 hours, 7 days a week

Visit [www.cdc.gov/vsafe](https://www.cdc.gov/vsafe)



## FACT SHEET FOR RECIPIENTS AND CAREGIVERS

### EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Janssen COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of receiving the Janssen COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Janssen COVID-19 Vaccine may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Janssen COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Janssen COVID-19 Vaccine.

The Janssen COVID-19 Vaccine is administered as a **single dose**, into the muscle.

The Janssen COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit [www.janssencovid19vaccine.com](http://www.janssencovid19vaccine.com).

#### WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

##### WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Common symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

##### WHAT IS THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Janssen COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the “**What is an Emergency Use Authorization (EUA)?**” section at the end of this Fact Sheet.

## **WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE JANSSEN COVID-19 VACCINE?**

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies,
- have a fever,
- have a bleeding disorder or are on a blood thinner,
- are immunocompromised or are on a medicine that affects your immune system,
- are pregnant or plan to become pregnant,
- are breastfeeding,
- have received another COVID-19 vaccine,

## **WHO SHOULD GET THE JANSSEN COVID-19 VACCINE?**

FDA has authorized the emergency use of the Janssen COVID-19 Vaccine in individuals 18 years of age and older.

## **WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?**

You should not get the Janssen COVID-19 Vaccine if you:

- had a severe allergic reaction to any ingredient of this vaccine.

## **WHAT ARE THE INGREDIENTS IN THE JANSSEN COVID-19 VACCINE?**

The Janssen COVID-19 Vaccine includes the following ingredients: recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl- $\beta$ -cyclodextrin (HBCD), polysorbate-80, sodium chloride.

## **HOW IS THE JANSSEN COVID -19 VACCINE GIVEN?**

The Janssen COVID-19 Vaccine will be given to you as an injection into the muscle.

The Janssen COVID-19 Vaccine vaccination schedule is a **single dose**.

## **HAS THE JANSSEN COVID-19 VACCINE BEEN USED BEFORE?**

The Janssen COVID-19 Vaccine is an unapproved vaccine. In an ongoing clinical trial, 21,895 individuals 18 years of age and older have received the Janssen COVID-19 Vaccine.

## **WHAT ARE THE BENEFITS OF THE JANSSEN COVID-19 VACCINE?**

In an ongoing clinical trial, the Janssen COVID-19 Vaccine has been shown to prevent COVID-19 following a single dose. The duration of protection against COVID-19 is currently unknown.

## **WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?**

Side effects that have been reported with the Janssen COVID-19 Vaccine include:

- Injection site reactions: pain, redness of the skin and swelling.
- General side effects: headache, feeling very tired, muscle aches, nausea, and fever.

There is a remote chance that the Janssen COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Janssen COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing,
- Swelling of your face and throat,
- A fast heartbeat,
- A bad rash all over your body,
- Dizziness and weakness.

Blood clots involving blood vessels in the brain, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Janssen COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two-weeks following vaccination. Most people who developed these blood clots and low levels of platelets were females ages 18 through 49 years. The chance of having this occur is remote. You should seek medical attention right away if you have any of the following symptoms after receiving Janssen COVID-19 Vaccine:

- Shortness of breath,
- Chest pain,
- Leg swelling,
- Persistent abdominal pain,
- Severe or persistent headaches or blurred vision,
- Easy bruising or tiny blood spots under the skin beyond the site of the injection.

These may not be all the possible side effects of the Janssen COVID-19 Vaccine. Serious and unexpected effects may occur. The Janssen COVID-19 Vaccine is still being studied in clinical trials.

### **WHAT SHOULD I DO ABOUT SIDE EFFECTS?**

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include “Janssen COVID-19 Vaccine EUA” in the first line of box #18 of the report form.

In addition, you can report side effects to Janssen Biotech, Inc. at the contact information provided below.

<b>e-mail</b>	<b>Fax number</b>	<b>Telephone numbers</b>
JNJvaccineAE@its.jnj.com	215-293-9955	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

You may also be given an option to enroll in **v-safe**. **V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: [www.cdc.gov/vsafe](http://www.cdc.gov/vsafe).

### **WHAT IF I DECIDE NOT TO GET THE JANSSEN COVID-19 VACCINE?**

It is your choice to receive or not receive the Janssen COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

### **ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES JANSSEN COVID-19 VACCINE?**

Currently, there is no FDA approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

### **CAN I RECEIVE THE JANSSEN COVID-19 VACCINE WITH OTHER VACCINES?**

There is no information on the use of the Janssen COVID-19 Vaccine with other vaccines.

## WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

## WILL THE JANSSEN COVID-19 VACCINE GIVE ME COVID-19?


No. The Janssen COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

## KEEP YOUR VACCINATION CARD

When you receive the Janssen COVID-19 Vaccine, you will get a vaccination card to document the name of the vaccine and date of when you received the vaccine.

## ADDITIONAL INFORMATION

If you have questions or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, scan the QR code using your device, visit the website or call the telephone numbers provided below.

QR Code	Fact Sheets Website	Telephone numbers
	<a href="http://www.janssencovid19vaccine.com">www.janssencovid19vaccine.com</a> .	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

## HOW CAN I LEARN MORE?

- Ask the vaccination provider.
- Visit CDC at <https://www.cdc.gov/coronavirus/2019-ncov/index.html>.
- Visit FDA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

Contact your local or state public health department.

## WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. For more information about IISs visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.



## **CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?**

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients).

## **WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?**

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.

## **WHAT IS THE COUNTERMEASURE INJURY COMPENSATION PROGRAM?**

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses for certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit [www.hrsa.gov/cicp](http://www.hrsa.gov/cicp) or call 1-855-266-2427.

## **WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?**

The United States FDA has made the Janssen COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Janssen COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Janssen COVID-19 Vaccine is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Manufactured by:  
Janssen Biotech, Inc.  
a Janssen Pharmaceutical Company of Johnson & Johnson  
Horsham, PA 19044, USA



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For more information, call US Toll Free: 1-800-565-4008, US Toll: (908) 455-9922 or go to [www.janssencovid19vaccine.com](http://www.janssencovid19vaccine.com)

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Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

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