TEXAS Health and Human Services | Texas Department of State Health Services

ImmTrac2 Immunization Registry
DISASTER INFORMATION RETENTION CONSENT FORM

(Please print clearly)

Client's Last Name

Client's First Name

Client's Middle Name

Client's Date of Birth (__/__/____)

*A parent, legal guardian or managing conservator must sign this form if the client is younger than 18 years of age.

Client's Gender: ☐ Male ☐ Female

Client's Address

Apartment #

Client's Telephone (___-___-____)

City

State

Zip Code

County

Mother's First Name (if client is younger than 18 years of age)

Mother's Maiden Name (if client is younger than 18 years of age)

ImmTrac2, the Texas immunization registry, has been designated as the disaster-related reporting and tracking system for immunizations, antivirals, and other medications administered to individuals in preparation for, or in response to, a disaster or public health emergency. From the time the event is declared over, ImmTrac2 will retain disaster-related information received from health-care providers for a period of 5 years. At the end of the 5 year retention period, client-specific disaster-related information will be removed from the Registry unless consent is granted to retain the client information in ImmTrac2 beyond the 5 year retention period.

The Texas Department of State Health Services (DSHS) encourages your voluntary participation in the Texas immunization registry.

Consent for Retention of Disaster-Related Information and Release of Information to Authorized Entities

I understand that, by granting the consent below, I am authorizing retention of my (or my child's) disaster-related information by DSHS beyond the 5 year retention period. I further understand that DSHS will include this information in the state's central immunization registry ("ImmTrac2"). Once in ImmTrac2, my (or my child's) disaster-related information may by law be accessed by:

- a state agency, for the purpose of aiding and coordinating communicable disease prevention and control efforts, and / or
- a physician or other health-care provider legally authorized to administer immunizations, antivirals, and other medications, for treating the client as a patient;

I understand that I may withdraw this consent to retain information in the ImmTrac2 Registry beyond the 5 year retention period and my consent to release information from the Registry, at any time by written communication to the Texas Department of State Health Services, ImmTrac2 Group – MC 1946, P. O. Box 149347, Austin, Texas 78714-9347.

By my signature below, I GRANT consent to retain my disaster-related information (or my child's information if younger than age 18) in the Texas immunization registry beyond the 5 year retention period.

Client (or parent, legal guardian, or managing conservator): _____

Printed Name:

Date:_____ Signature: _____

Privacy Notification: With few exceptions, you have the right to request and be informed about information that the State of Texas collects about you. You are entitled to receive and review the information upon request. You also have the right to ask the state agency to correct any information that is determined to be incorrect. See http://www.dshs.texas.gov for more information on Privacy Notification. (Reference: Government Code, Section 552.021, 552.023, 559.003, and 559.004)

Upon completion, please fax or mail form to the DSHS ImmTrac2 Group or a registered Health-care provider.

Questions? (800) 252-9152 • (512) 776-7284 • Fax: (866) 624-0180 • www.ImmTrac.com • ImmTrac2 DC

Texas Department of State Health Services • ImmTrac2 Group – MC 1946 • P. O. Box 149347 • Austin, TX 78714-9347

PROVIDERS REGISTERED WITH ImmTrac2

Please enter client information in ImmTrac2 and **affirm** that consent has been granted.

DO NOT fax to ImmTrac2. **Retain this form in your client's record.**

Office User Only

COVID Vaccine Consent Form

Full, Legal Name (First Name Middle Initial. Last Name)		**Site/Facility**	
Email Address		**Race**	**Ethnicity**
Address		**Birth Date** (month / day / year)	**Age** **Sex** Sex
City	**Zip Code**	**Primary Phone #**	**Secondary Phone #**
Insurance Company:	**Member ID:**	**Group #:**	
Policy Holder's Name:	**Policy Holder's Date of Birth:**		

The current health care laws require us to bill your insurance company for the vaccine. There will be no out of pocket expense for those insured.

Vaccine(s) to be given:

☐ COVID #1

THE COVID VACCINE YOU RECEIVED WILL BE REPORTED TO IMMTRAC2 WITHIN 24 HOURS OF ADMINISTRATION.
IF YOU HAVE ANY HEALTH QUESTIONS, PLEASE CONTACT YOUR PRIMARY CARE PHYSICIAN OR CALL AURORA CONCEPTS AT 936-598-3296 TO SPEAK TO A NURSE

_____ _____ _____

Printed Name Signature Date

FOR ONSITE USE ONLY

I acknowledge that Aurora Concepts provided me, and I have been afforded the opportunity to read, the *COVID-19 Vaccine Fact Sheet* and the *Notice of Privacy Practices*.

_____ _____ _____

Printed Name Signature Date

AREA FOR OFFICIAL USE ONLY FOR ADMINISTRATION

	1	2	3	4	5	6
Clinic/Office Address	Aurora Concepts 233 Hurst St, Ste B Center, TX 75935	Aurora Concepts 233 Hurst St, Ste B Center, TX 75935	Aurora Concepts 233 Hurst St, Ste B Center, TX 75935	Aurora Concepts 233 Hurst St, Ste B Center, TX 75935	Aurora Concepts 233 Hurst St, Ste B Center, TX 75935	Aurora Concepts 233 Hurst St, Ste B Center, TX 75935
Date & Time VIS Given						
Vaccine Given						
Date Vaccine Administered						
Vaccine Manufacturer						
Vaccine Lot Number						
Site of Administration						
Signature of Vaccine Administrator						
Title of Vaccine Administrator						

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.

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-β-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.

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.

e-mail	Fax number	Telephone numbers
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.

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
	www.janssencovid19vaccine.com.	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 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

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

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

Revised: Mar/19/2021

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

Barcode Date: 02/2021