

## Pfizer-BioNTech COVID-19 Vaccine Consent and Screening Form for Individuals Under 18 Years of Age

### Section 1: Information About Minor Child to Receive Vaccine (please print)

MINOR'S NAME (Last)		(First)	(M.I.)	MINOR'S DATE OF BIRTH (MM/DD/YEAR):	
<b>MINOR'S RACE</b> <input type="checkbox"/> White <input type="checkbox"/> Black <input type="checkbox"/> Asian <input type="checkbox"/> Native American or Alaska Native <input type="checkbox"/> Native Hawaiian or Pacific Islander			<b>ETHNICITY</b> <input type="checkbox"/> Hispanic <input type="checkbox"/> Non-Hispanic		
PARENT/LEGAL GUARDIAN'S NAME (Last)		(First)	(M.I.)	MINOR'S AGE:	MINOR'S GENDER: M / F
ADDRESS			PARENT/GUARDIAN DAYTIME PHONE NUMBER <u>AND</u> MOBILE NUMBER:		
CITY	STATE	ZIP			

**Section 2: Screening for Vaccine Eligibility** The following questions will help determine if there is any reason your child should not get the COVID-19 vaccine. **If you answer "yes" to any question, it does not necessarily mean that your child should not be vaccinated.** It just means additional questions may be asked. If a question is not clear, please ask your healthcare provider to explain it.

	YES	NO	UNKNOWN
1. Is your child currently feeling sick or ill?			
2. Has your child ever received a dose of the COVID-19 vaccine? If yes, which vaccine? <input type="checkbox"/> Moderna; <input type="checkbox"/> Pfizer; <input type="checkbox"/> Janssen (Johnson & Johnson); <input type="checkbox"/> another brand of vaccine: _____ Date: _____			
3. Has your child ever had an allergic reaction to: <i>(This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that caused hives, swelling, or respiratory distress, including wheezing.)</i>			
• A component of a COVID-19 vaccine, including any of the following:			
○ Polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures?			
○ Polysorbate, which is found in some vaccines, film coated tablets, and intravenous steroids?			
• A previous dose of COVID-19 vaccine?			
4. Has your child ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or an injectable medication? <i>(This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that caused hives, swelling, or respiratory distress, including wheezing.)</i>			

5. Check all that apply to your child:

- Had a severe allergic reaction to something other than a vaccine or injectable therapy such as food, pet, venom, environmental or oral medication allergies
- Had COVID-19 and was treated with monoclonal antibodies or convalescent serum
- Diagnosed with Multisystem Inflammatory Syndrome (MIS-C or MIS-A) after a COVID-19 infection
- Has a weakened immune system (i.e., HIV infection, cancer)
- Takes immunosuppressive drugs or therapies
- Has a bleeding disorder

- Takes a blood thinner
- Has a history of heparin-induced thrombocytopenia (HIT)
- Is currently pregnant or breastfeeding
- Has received dermal fillers

**Section 3: Information on the risks and benefits of the PfizerBioNTech COVID-19 Vaccine**

The Pfizer-BioNTech COVID-19 Vaccine may prevent the person vaccinated from getting COVID-19. There is no U.S. Food and Drug Administration (FDA)-approved vaccine to prevent COVID-19. However, the FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals twelve (12) years of age and older under an Emergency Use Authorization (EUA). The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone. Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include injection site pain, tiredness, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, feeling unwell, and swollen lymph nodes. There is a remote chance that the Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 Vaccine. For this reason, a vaccination provider may ask the person receiving the vaccine to stay at the place where they received their vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include difficulty breathing, swelling of the face and throat, a fast heartbeat, and/or a bad rash all over the body.

**Section 4: Consent**

I have reviewed the information on risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine in Section 3 above and understand the risks and benefits. In providing my consent below, I agree that:

1. I have reviewed this consent and screening form.
2. I have read or had read to me the latest (i.e. most recently released) version of the FACT SHEET FOR RECIPIENTS AND CAREGIVERS; EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 12 YEARS OF AGE AND OLDER, available at <https://www.cvdvaccine.com/> or <https://www.fda.gov/media/144414/download>.
3. I have the legal authority to consent to have the minor child named above vaccinated with the Pfizer-BioNTech COVID-19 Vaccine, which consists of two (2) doses administered 21 days apart.
4. I understand that I am not required to accompany the child named above to their vaccination appointment and that, by giving my consent below, the child may receive the Pfizer-BioNTech COVID-19 Vaccine whether or not I am present at the vaccination appointment.
5. If I have health insurance that covers the child named above, I give permission for my insurance company to be billed for the costs of administering the PfizerBioNTech COVID-19 Vaccine. The government is paying for the Pfizer-BioNTech COVID-19 Vaccine itself, and I will not be billed for that portion of the cost of my immunization.
6. I understand that pursuant to state law, all immunizations will be inputted to the Louisiana Immunization Network (LINKS) registry operated by the Louisiana Department of Health. More information about LINKS can be found at <https://ldh.la.gov/index.cfm/page/3660>.

I GIVE CONSENT to \_\_\_\_\_ [INSERT VACCINATING ENTITY NAME] to vaccinate the minor child named at the top of this form with the Pfizer-BioNTech COVID-19 Vaccine and have reviewed and agree to the information included in Section 4 of this form.

Date signed: month \_\_\_\_ day \_\_\_\_ year \_\_\_\_

Signature of the Parent/Legal Guardian named above

Manufacturer	Lot #	Expiration Date	Route	Dose	Injection site	EUA Date
Pfizer-BioNTech			Intramuscular (IM)	0.3mL		5/10/2021
Moderna			Intramuscular (IM)	0.5mL		3/26/2021
Janssen			Intramuscular (IM)	0.5mL		4/23/2021

## **FACT SHEET FOR RECIPIENTS AND CAREGIVERS**

### **EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 12 YEARS OF AGE AND OLDER**

You are being offered the Pfizer-BioNTech 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 the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Pfizer-BioNTech COVID-19 Vaccine is a vaccine and 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 Pfizer-BioNTech COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Pfizer-BioNTech COVID-19 Vaccine.

The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

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

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

### **WHAT IS COVID-19?**

COVID-19 disease 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. 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 PFIZER-BIONTECH COVID-19 VACCINE?**

The Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 12 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 PFIZER-BIONTECH COVID-19 VACCINE?**

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

- have any allergies
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- 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
- have ever fainted in association with an injection

**WHO SHOULD GET THE PFIZER-BIONTECH COVID-19 VACCINE?**

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 12 years of age and older.

**WHO SHOULD NOT GET THE PFIZER-BIONTECH COVID-19 VACCINE?**

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

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

**WHAT ARE THE INGREDIENTS IN THE PFIZER-BIONTECH COVID-19 VACCINE?**

The Pfizer-BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

**HOW IS THE PFIZER-BIONTECH COVID-19 VACCINE GIVEN?**

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

The Pfizer-BioNTech COVID-19 Vaccine vaccination series is 2 doses given 3 weeks apart.

If you receive one dose of the Pfizer-BioNTech COVID-19 Vaccine, you should receive a second dose of this same vaccine 3 weeks later to complete the vaccination series.

**HAS THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?**

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine.

**WHAT ARE THE BENEFITS OF THE PFIZER-BIONTECH COVID-19 VACCINE?**

In an ongoing clinical trial, the Pfizer-BioNTech COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 3 weeks apart. The duration of protection against COVID-19 is currently unknown.

**WHAT ARE THE RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE?**

There is a remote chance that the Pfizer-BioNTech 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 Pfizer-BioNTech 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

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the Pfizer-BioNTech COVID-19 Vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of the Pfizer-BioNTech COVID-19 Vaccine. The chance of having this occur is very low. You should seek medical attention right away if you have any of the following symptoms after receiving the Pfizer-BioNTech COVID-19 Vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

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

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain

- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- diarrhea
- vomiting
- arm pain

These may not be all the possible side effects of the Pfizer-BioNTech COVID-19 Vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech 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 "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

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

Website	Fax number	Telephone number
<a href="http://www.pfizersafetyreporting.com">www.pfizersafetyreporting.com</a>	1-866-635-8337	1-800-438-1985

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 second-dose reminders if needed and 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 PFIZER-BIONTECH COVID-19 VACCINE?**

It is your choice to receive or not receive the Pfizer-BioNTech 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 PFIZER-BIONTECH COVID-19 VACCINE?**

Currently, there is no 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 PFIZER-BIONTECH COVID-19 VACCINE WITH OTHER VACCINES?**

There is no information on the use of the Pfizer-BioNTech 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 PFIZER-BIONTECH COVID-19 VACCINE GIVE ME COVID-19?**

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


**KEEP YOUR VACCINATION CARD**

When you get your first dose, you will get a vaccination card to show you when to return for your second dose of Pfizer-BioNTech COVID-19 Vaccine. Remember to bring your card when you return.

**ADDITIONAL INFORMATION**

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

<b>Global website</b>	<b>Telephone number</b>
<p data-bbox="290 1272 568 1302"><a href="http://www.cvdvaccine.com">www.cvdvaccine.com</a></p> 	<p data-bbox="857 1318 1094 1381">1-877-829-2619 (1-877-VAX-CO19)</p>

## **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. This will ensure that you receive the same vaccine when you return for the second dose. 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, Health Resources & Services Administration [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 <https://TIPS.HHS.GOV>.

## **WHAT IS THE COUNTERMEASURES 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 of 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 Pfizer-BioNTech 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 Pfizer-BioNTech 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, 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 in the treatment of patients during the COVID-19 pandemic.

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



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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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