

**Phelps Health – Occupational Health & Wellness  
 COVID-19 Vaccination Consent under Emergency Use Authorization**

**PATIENT DEMOGRAPHIC INFORMATION**

*Last Name: _____		*First Name: _____		Middle Initial: _____
*Date of Birth / / _____		*Sex: Male <input type="checkbox"/> Female <input type="checkbox"/> Transgendered <input type="checkbox"/> Other <input type="checkbox"/>		
*Race White <input type="checkbox"/> Black <input type="checkbox"/> Asian <input type="checkbox"/> Pacific Islander <input type="checkbox"/>		Hispanic Ethnicity: Yes <input type="checkbox"/> No <input type="checkbox"/>		
American Indian/Alaskan Native <input type="checkbox"/> None Specified <input type="checkbox"/> Refused <input type="checkbox"/>		Unknown <input type="checkbox"/> Refused <input type="checkbox"/>		
Address: _____				City: _____
State: _____	Zip: _____	County: _____		Phone number: _____
Email: _____		Would like a reminder for the next appointment Yes <input type="checkbox"/> or No <input type="checkbox"/> postcard/call/text		
Private or employer insurance <input type="checkbox"/>		Underinsured <input type="checkbox"/>		Uninsured <input type="checkbox"/> Medicaid <input type="checkbox"/>

**HEALTH HISTORY**

	<u>YES</u>	<u>NO</u>	<u>UNKNOWN</u>
1. Are You moderately or severely ill today? (mild illnesses or taking antibiotics are not reasons to withholding vaccination)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Do You have any allergies to foods or medications? If yes, please list	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Have you ever had a serious reaction after a vaccination?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. In the past 14 days have you Tested Positive for COVID-19?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Had Contact with another person with lab confirmed COVID-19?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Had any other vaccination?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. In the past year, have you been diagnosed with COVID-19? If yes, date of diagnosis: ____/____/____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Are you breastfeeding, pregnant or planning on becoming pregnant in the next six months?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. In the past 3 months, have you taken medications that affect your immune system? <i>Such as prednisone, other steroids, anticancer drugs, drugs for treatment of rheumatoid arthritis, HIV/AIDS, Crohn's disease or psoriasis; or have you had radiation treatments</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Do you currently have or a history of neurological condition, seizure or have ever had Guillain Barré Syndrome?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. In the past year, have you received a dose of COVID-19 vaccine?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the CICP to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the covered countermeasures. The CICP can also provide benefits to certain survivors of individuals who die as a direct result of the administration or use of covered countermeasures identified in a PREP Act declaration. The PREP Act declaration for medical countermeasures against COVID-19 states that the covered countermeasures are any antiviral medication, any other drug, any biologic, any diagnostic, any other device, or any vaccine used to treat, diagnose, cure, prevent, or mitigate COVID-19, the transmission of SARS-CoV-2 or a virus mutating from SARS-CoV-2, or any device used in the administration of and all components and constituent materials of any such product. Information about the CICP and filing a claim is available by calling 1-855-266-2427 or visiting <http://www.hrsa.gov/cicp/>.

PLEASE PRINT NAME of signature below

SIGNATURE OF PATIENT	RELATIONSHIP TO CLIENT	TODAY'S DATE
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For Clinic Use only

<b>*Manufacturer</b>	<b>Brand</b>	<b>*Lot number</b>
Dose number 1 <input type="checkbox"/> or 2 <input type="checkbox"/>	<b>*Exp. Date:</b> ___/___/___	<b>*vaccine dosage:</b>
<b>*EUA fact sheet date:</b> ___/___/___	<b>* EUA fact sheet given date:</b> ___/___/___	<b>Injection Site (Deltoid)    L <input type="checkbox"/> R <input type="checkbox"/></b>
<b>*Administered by Name &amp; Title :</b>		
<b>*Date Administered:</b> ___/___/___		
<b>*Agency: Phelps Health – Occupational Health &amp; Wellness</b>		
<b>*Agency Address: 1000 West Tenth Street Rolla, MO 65401</b>		
<b>*Clinic administration address: 1000 West Tenth Street Rolla, MO 65401</b>		

## **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 16 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 16 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 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 PFIZER-BIONTECH COVID-19 VACCINE?**

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 16 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 20,000 individuals 16 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?**

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
- swollen lymph nodes (lymphadenopathy)

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.

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 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

**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. FDA may allow the emergency use of other vaccines to prevent COVID-19.

**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.

Global website	Telephone number
<p data-bbox="337 442 634 470"><a href="http://www.cvdvaccine.com">www.cvdvaccine.com</a></p> 	<p data-bbox="956 491 1214 559">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>.

## 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).



Manufactured by  
Pfizer Inc., New York, NY 10017

**BIONTECH**

Manufactured for  
BioNTech Manufacturing GmbH  
An der Goldgrube 12  
55131 Mainz, Germany

LAB-1451-0.7

Revised: December 2020



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

Barcode Date: 12/2020



Physicians with Phelps Health privileges are included in this group. The vaccine is Pfizer BioNTech, attached is an info sheet. Please let me know if it doesn't open.

**Please note:** be sure to review the following and attached information. In order for the vaccination clinics to flow as smoothly as possible, we need you to understand and follow the process, which includes entering the vaccination clinic from the right location and filling out paperwork prior to arriving for your vaccination.

**When will I be vaccinated?**

The vaccinations will be for employees who have expressed interest, and this first round of vaccinations for employees will occur today and over the next 10-day period. Please see the attached schedule that designates the dates each department leader should have their employees attend the vaccination clinic. The employee groups are divided by department and last name.

Vaccination clinic times will be from 0730-1930 (7:30 AM – 7:30 PM) on the following days:

Monday, January 4  
Tuesday, January 5  
Wednesday, January 6  
Thursday, January 7  
Friday, January 8

**You are expected to attend the vaccination clinic on the date your department is scheduled based on your last name. Your date to arrive may occur on New Year's Day or the weekend. Please plan accordingly!** What should I bring with me?

Please fill out the attached consent form prior to your scheduled vaccination date and bring the form with you. In addition, please bring the attached Pfizer COVID-19 Vaccination Fact Sheet to the vaccination clinic. We will go over this important information with you.

**How do I enter the vaccination clinic?**

The entrance to the vaccination clinic will be outside of the DDCI patio area near where the waterfall feature and donor wall is located. **You will not be able to enter the vaccination clinic from inside the DDCI.** To enter, please use doors D18 and D19. Employees waiting to be vaccinated should remain socially distanced and line up outside of the building in the patio area. You may want to bring a coat to wear while you wait.

**How long will the vaccination process take?**

You may be at the vaccination clinic for a while, depending on the line of people waiting ahead of you when you arrive. In addition, after you receive the vaccination you will be monitored for possible side effects for at least 15 minutes. The 15-minute monitoring time is mandatory. Please plan ahead.

**Rhonda Borders, CPCS**

Senior Medical Staff Coordinator

Medical Staff Office

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