PharmScript COVID-19 Vaccination Informed Consent Form Instruction Sheet

Please read below for instructions on how to complete the PharmScript COVID-19 Vaccination Informed Consent Form:

Sections 1–3 must be completed prior to Clinic Day.

SECTION 1

Patient Information

This section must be completed for any resident or facility staff that will receive the COVID-19 Vaccine. All fields are required.

SECTION 2

Healthcare Worker Information

This section must be completed for any facility staff that will receive the COVID-19 Vaccine. This section does not need to be completed for residents.

SECTION 3

Consent

This section must be completed for any resident or facility staff that will receive the COVID-19 Vaccine.

PHARMSCRIPT

SECTION 1: PATIENT INFORMATION

This section must be completed for residents/facility staff receiving the vaccine.

First Name:	Last Name:
Date of Birth:	Gender: ☐ Male ☐ Female
Allergies:	☐ No Known Drug Allergies
Facility Name & Address:	

Race/Ethnicity: ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Hispanic or Latino American ☐ Pacific Islander ☐ White ☐ Other, specify:

Mother's First Name: ☐ Unavailable	Mother's Maiden Name: ☐ Unavailable

Patient Guardian Type (Please select from the options below):

☐ Aunt (AUN)	☐ Child (CHD)	☐ Guardian (GRD)	☐ Parent (PAR)	☐ Sister (SIS)	☐ Uncle (UNC)
☐ Brother (BRO)	☐ Foster Child (FCHI)	☐ Grandparent (GRP)	☐ Self (SEL)	☐ Spouse (SPO)	☐ Other (OTH):
☐ Caregiver (CGV)	☐ Father (FTH)	☐ Mother (MTH)	☐ Sibling (SIB)	☐ Stepchild (SCH)	☐ Unavailable

I consent to receive the following vaccination(s) [Vaccine]: SARS-CoV-2 Vaccine (2-dose series) ☐ Yes ☐ No

SECTION 2: HEALTHCARE WORKER INFORMATION

Facility Staff receiving the vaccine must complete section 2 below.

Medical Conditions:			
Mailing Address:			
Street:	City:	State:	Zip:
Personal Phone Number:	Personal Email Address:		
Primary Care Provider (PCP):	PCP Phone Number:		

Insurance Information (Please fill table below or check "No Insurance" if not insured)

☐ **No Insurance**	**Pharmacy/Medication**	**Medical**
Insurance Plan/Plan ID		
Member/Recipient ID Number		
RX BIN		N/A
RX PCN		N/A
Group Number		

Are you the cardholder? ☐ Yes ☐ No If no, please provide the Cardholder's name, date of birth and relationship below:

Cardholder Name:	Cardholder DoB:	Relationship to Cardholder:

SECTION 3: CONSENT

Please read the following statements and sign below on the signature line.

I have received, read and understand the COVID-19 Vaccine Information provided by PharmScript. I hereby authorize PharmScript and the practitioners employed by or contracted with PharmScript (each, a "Provider") to administer the Vaccine I have requested above as a two-dose regimen series administered 19 to 23 days apart (the "Services"). The scope of this consent includes discussion about the vaccine(s) and its administration between PharmScript and other health care professionals for purposes of care and treatment. I understand that I may withdraw this consent at any time by making a request in writing.

Continued on next page.

SECTION 3: CONSENT

Please read the following statements and sign below on the signature line.

I acknowledge that I have been informed about, the following:

- The goal of the Services is to administer the Vaccine I requested.
- The Provider(s) will provide me with additional information about any risks associated with the Services, which depend upon my specific diagnoses and health status.
- Administering Vaccines is not an exact science and there are no guarantees as to the results of the Services that may be provided to me.
- The nature and purpose of the Services, expected benefits, potential known and unknown complications, likelihood of achieving goals, and relative risks that may arise from the Services, along with the relevant risks and consequences of no treatment.

I understand the benefits and risks of the Vaccine and I expressly consent, request, and authorize the administration of the Vaccine. On behalf of myself, my heirs and personal representatives, I hereby release and hold harmless PharmScript, each Provider and the applicable staff, agents, successors, divisions, affiliates, subsidiaries, officers, directors, contractors and employees from any and all liability or claims, whether known or unknown, arising out of, in connection with, or in any way related to the Services.

I acknowledge that: (a) I understand the purposes/benefits of my state's vaccination registration ("State Registry") and my state's health information exchange ("State HIE"); and (b) the Provider may disclose my vaccination information to the State Registry, to the State HIE, or through the State HIE to the State Registry, for purposes of public health reporting, or to my healthcare providers enrolled in the State Registry and/or State HIE for purposes of care coordination.

I further authorize the applicable Provider to: (a) release my medical or other information, including my communicable disease (including HIV), mental health and drug/alcohol abuse information, to, or through, the State HIE to my healthcare professionals, Medicare, Medicaid, or other third-party payers as necessary to effectuate care or payment; (b) submit a claim to my insurer for the Services; and (c) request payment or authorized benefits be made on my behalf to the applicable Provider with respect to the Services.

I acknowledge that, depending upon my state's law, I may prevent, by using a state-approved opt-out form or, as permitted by my state law, an opt-out form ("Opt-Out Form") furnished by the Provider: (a) the disclosure of my vaccination information by the Provider to the State HIE and/or State Registry; or (b) the State HIE and/or State Registry from sharing my vaccination information with any of my other healthcare providers enrolled in the State Registry and/or State HIE. The Provider will, if my state permits, provide me with an Opt-Out Form. I understand that I may need to consent, depending on my state's law, and to the extent so required, I hereby do consent by signing below to the Provider reporting my vaccination information to the State HIE, or through the State HIE and/or State Registry to the entities and for the purposes described in this Informed Consent Form. Unless I provide the Provider with a signed Opt-Out Form, I understand that my consent will remain in effect until I withdraw my permission and that I may withdraw my consent by providing a completed Opt-Out Form to the Provider and/or my State HIE, as applicable. I understand that even if I do not consent or if I withdraw my consent, my state's laws may permit certain disclosures of my vaccination information to or through the State HIE as required or permitted by law.

Photocopies/electronic transmissions/faxes of this consent and any signatures are to be considered as valid originals.

MY SIGNATURE BELOW INDICATES THAT I VOLUNTARILY AGREE TO ALL OF THE ABOVE AND THAT THE NATURE OF THIS CONSENT WAS EXPLAINED TO ME AND THAT I HAD THE OPPORTUNITY TO ASK ANY AND ALL QUESTIONS REGARDING THE ABOVE AND MY QUESTIONS HAVE BEEN ANSWERED TO MY SATISFACTION. I UNDERSTAND THE BENEFITS AND RISKS OF THE VACCINE AND I EXPRESSLY CONSENT, REQUEST AND AUTHORIZE THE ADMINISTRATION OF THE VACCINE. I HAVE BEEN PROVIDED WITH THE CDC'S VACCINE INFORMATION SHEET(S) OR THE EMERGENCY USE AUTHORIZATION (EUA) PATIENT FACT SHEET CORRESPONDING TO THE VACCINE THAT I AM RECEIVING.

If signing on behalf of the patient, please provide the following information:

☐ I am the legal and authorized representative of the patient and am authorized to sign this consent on the patient's behalf.

☐ The patient verbally agreed to all of the above and provided verbal consent but is unable to physically sign this consent form. Patient has verbally provided me with authorization to sign this consent on patient's behalf.

☐ The legal and authorized representative of the patient verbally agreed to all of the above on behalf of patient and provided verbal consent on behalf of the patient and verbal authorization for this consent to be signed.

Print Name (Signatory):	Signature:	Date:

Guardian Name:

Relationship to Patient (if applicable): ☐ Spouse ☐ Power of Attorney ☐ Legal Guardian ☐ Other, Please Specify:
(If "Other", refer to witness section)

Witness (use for Relationship To Patient is "Other"): (optional)

Signature:	Print Name:

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.

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 <u>NOT</u> 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
www.pfizersafetyreporting.com	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
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

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/ 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

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

LAB-1451-0.7

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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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