

### **VACCINATION CONSENT FORM**

### Pfizer-BioNTech COVID-19 Vaccine

The novel coronarvirus SARS-CoV-2 (a/k/a COVID-19) is an infectious disease that appeared in late 2019. 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 at this time.

•	t that the Pfizer-BioNTed am authorized to make t	h COVID-19 Vaccine be given to r nis request (select one):	me or to the pe			
Recipie	nt's Information:					
Last Nar	me	First Name		Date of Birth	Gender	
Address City:	:	State:		Zip:		
		ation (complete if different from				
Last Nar	me	First Name		Date of Birth	Gender	
Address City:	:	State:		Zip:		
	WLEDGEMENTS (INITI	AL EACH STATEMENT):				
	connection with the or was directed to the	I was given a copy of the FDA's Emergency Use Authorization (EL e FDA's COVID-19 vaccination w	JA) for the Pfiz	zer-BioNTech COV	ID-19 Vaccine	
	cvdvaccine.com.  FDA has authorized FDA-approved vacci	the emergency use of the Pfizer- ne.	-BioNTech CO	VID-19 Vaccine, w	hich is not an	
	TI 1 17 11 10 11 11 11 11 11 11 11 11 11 11 11					
	mL each) 3 weeks	The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) 3 weeks apart. Recipients must receive both doses of the Pfizer-BioNTech COVID-19 Vaccine to complete vaccination.				
	Recipient is 16 years	s of age or older.				
	Immunocompromise a diminished immun	d persons, including individuals re e response to the Pfizer-BioNTech	ceiving immun COVID-19 Va	osuppressant thera	apy, may have	
	Vaccine may not pro	tect all vaccine recipients.				

	The Pfizer-BioNTech COVID hydroxybutyl)azanediyl)bis(he ditetradecylacetamide, 1,2-D chloride, monobasic potassiul sucrose.	exane-6,1-diyl)bis(2- Distearoyl-sn-glycero	hexyldecanoate), 2 [(polyeth) -3- phosphocholine, and	ylene glycol) cholesterol),	-2000]-N,N- potassium
	I have read or have had ex Recipients and Caregivers opportunity to discuss the ben choice before vaccination. satisfaction.	regarding the Pfiz efits and risks of thi	er-BioNTech COVID-19 Vas COVID-19 vaccine with a h	accine. I ha ealthcare pro	ve had an ovider of my
	I believe I understand the ben the person named for whom I	efits and risks of thi am authorized to m	s vaccine and ask that this vanake this request.	accine be giv	en to me or
about a a "yes"	AL SCREENING QUESTIONS: C Il your medical conditions, including response to any other question n proceeding. Answering "yes" to e	g if you answer "yes" neans you may wis	to any question. Except for the to consult with your individual	ne last two (2 dual healthca	) questions, are provider
		Question		Yes	No
Do	you have any allergies?				
Do	you have a fever?				
Do	you have a bleeding disorder or ar	e on a blood thinne	r?		
	you immunocompromised or are ytem?	you on a medicine t	hat affects your immune		
Are	you pregnant or plan to become p	regnant?			
Are	you breastfeeding?				
Ha	ve you received another COVID-19	vaccine?			
Ha	ve you had a severe allergic reaction	on after a previous o	dose of this vaccine?		
Ha	ve you had a severe allergic reaction	on to any ingredient	of this vaccine?		
Cimnati	une of Resimient OR Resimiently	A. 14b a viza d Ivadi: ide		Data	
Signati	ure of Recipient OR Recipient's A	Autnorizea inaiviau	aı	Date	
	WOITE IN THIS COACE OFFICE H	ISE ONLY VIS Editi	on Duovido de		
DO NO	WRITE IN THIS SPACE—OFFICE U	SE ONLY VIS Edition	on Providea:		
Vaccin	e:		Administration Date:		
	acturer:		Lot #:		
	ate:				
			l):		
<u> </u>		. Jidilio (III	,· <u> </u>		
Nurse/	Provider's Signature		Date	Time	<del>)</del>



# The Edward & Mary Lord Family Health Center at UCFS

47 Town Street Norwich, Connecticut 06360-2315

> Telephone (860) 892-7042 Fax (860) 886-6124 UCFShealthcare.org

### I DO **NOT** HAVE INSURANCE

### CONSENT FOR INSURANCE BILLING FOR CORONAVIRUS (COVID-19) VACCINATION

Name		_ Date of	Birth	Are you a	UCFS Patient? Yes/No (circle)
bill for the adm	inistration of th	e COVID-19	9 Vaccination.		urance information I authorize UCFS to hout health insurance or with ed.
Print Name of I	nsured Party				
	L	ast Name,	First Name,	Middle Initial,	Date of Birth
Your Relationsh	ip to Insured _	Self	Spouse	Other	
Primary Insurar	ice Company				
Member/Insure	ed ID #				
Group#				<del></del>	
Insurance Addre	ess (usually on	the back of	your card)		
Street/PO Box					
City	State		Zip Code		
Secondary Insu	rance Company	'			
Member/Insure Group#	ed ID #				
UCFS USE ONLY		• • • • • • • • • • • • • • • • • • • •			
Type of Vaccine Re	ceived Pfizer				













### **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.

1

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.

2

### 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?

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

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

3

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- 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 <a href="https://vaers.hhs.gov/reportevent.html">https://vaers.hhs.gov/reportevent.html</a>. 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

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.

# 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.

4

### 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 <a href="https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization">https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization</a>.
- 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: <a href="https://www.cdc.gov/vaccines/programs/iis/about.html">https://www.cdc.gov/vaccines/programs/iis/about.html</a>.

### 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

5

& 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 <a href="https://www.hrsa.gov/cicp/">www.hrsa.gov/cicp/</a> 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).

6



Manufactured by Pfizer Inc., New York, NY 10017

### BIONTECH Manufactured for

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

LAB-1451-3.2

Revised: 06 April 2021



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

Barcode Date: 12/2020

7



**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 get more information. 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.



After you receive your COVID-19 vaccine, visit **VSAFE.CDC.GOV** to set up your account.

### Frequently Asked Questions about v-safe

### How can I participate in v-safe?

Once you get a COVID-19 vaccine, you can enroll in **v-safe** using your smartphone. Your healthcare provider will give you an information sheet on **v-safe** that explains how to register and get started. **V-safe** is free to use — you will need a smartphone with a modern browser and access to the internet to participate. Participation is voluntary and you can opt out at any 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 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. Finally, you'll 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. 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 does my participation in v-safe make a difference?

By participating in v-safe, you can tell CDC if you have any side effects after a COVID-19 vaccine. This information helps CDC monitor the safety of COVID-19 vaccines in near real time. If any serious health problems are reported, they can be quickly investigated by CDC's medical experts and scientists. In addition, traditional vaccine safety systems, such as <u>Vaccine Adverse Event Reporting System</u> (VAERS) and the <u>Vaccine Safety Datalink (VSD)</u>, will also be used to monitor the safety of COVID-19 vaccines. These systems are part the nation's comprehensive approach to vaccine safety.

# What if I have a health problem I think is related to my COVID-19 vaccination between v-safe check-ins or after I've finished v-safe?

If at any time you have symptoms or health problems following COVID-19 vaccination that concern you, please contact your healthcare provider. In addition to your participation in **v-safe**, you can also <u>report your experience to VAERS</u>.



### Need help with v-safe?

Call 800-CDC-INFO (800-232-4636) TTY 888-232-6348 Open 24 hours, 7 days a week