



Office of Doctors Trujillo, deSchweinitz and ANP Carson-McCollum
9500 Independence Drive Suite 700 | Anchorage, AK 99507
p)907-569-3600 | f)907-569-3200
Email: frontdesk@akdocs.com
Website: www.akdocs.com

Pre-Vaccination Registration and Informed Consent for COVID-19 Immunization Packet
Pfizer-BioNTech COVID-19 Vaccine

COVER SHEET

Thank you for your interest in the COVID-19 vaccine! To get scheduled at our clinic:

Complete the 2-page Pre-Vaccination Registration Form on your computer/laptop and save it to your device and attach it in an email to: frontdesk@akdocs.com

Once you have sent the form, please wait for our call to schedule an appointment.

We will be offering appointments on Tuesdays and Wednesdays from:

- 9:00am – 11:30am and 1:00pm – 3:30pm (by appointment only)

Billing:

- The COVID-19 vaccine is free of charge.
- We will bill insurance for administration fee.
- If you are uninsured you will be automatically enrolled in the HRSA COVID-19 uninsured program.

Day of appointment: Please come inside the building (we are located in the southside of the building) and wait in the atrium near our office. You do not need to call or knock to check in; we will come out to the atrium for you at the time of your appointment.

Please bring photo ID and insurance card.

What to wear: Please wear a shirt that allows easy access to your upper arm.

Pre-Vaccination Registration and Informed Consent for COVID-19 Immunization

Trujillo, deSchweinitz, ANP Carson-McCollum

Date: _____

Privacy Practice Notification Received? ☐
Emergency Use Authorization Fact Sheet received? ☐

Participant's Information

First Name _____ Middle Initial _____ Last Name _____

Parent/Guardian First and Last Name: _____

Gender _____ Date of Birth _____ Age _____

Mailing Address: Street, City, State, Zip _____

Email _____

Home Phone _____ Cell Phone _____

Race _____

(American Indian/Alaska Native | Asian | White | Black/African American | Hawaiian/Pacific Islander | Other | Decline)

Hispanic/Latino? _____ (yes, no, decline)

Insurance Type _____

(Medicaid | Medicare | Tricare | Other Private Insurance | Uninsured)

Primary Insurance:	Secondary Insurance:	Driver's License/ID #:
ID/Subscriber #:	ID/Subscriber #: Group	
Group #:	#:	State Issued:

Do you have any of the following health conditions? _____

Asthma – Serious Heart Condition – Liver Disease – Chronic Lung Disease - Diabetes – Severe Obesity - Immunocompromised

COVID-19 Vaccine Screening Questions

	Yes	No	Don't Know
Are you feeling sick today?			
Have you ever received a dose of a COVID Vaccine? If yes, which vaccine product and date?			
Do you have allergies, such as to medications, foods or vaccine components?			
Have you ever had a serious allergic reaction (anaphylaxis) to a vaccine or any injectable?			
Have you received passive antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19? If yes, on what date?			
Have you received any other vaccines in the past 14 days?			
Do you have cancer, leukemia, HIV/AIDs, or take immunosuppressive treatments?			
Do you have a bleeding disorder or are you taking a blood thinner?			
For women: Are you pregnant or currently breastfeeding?			

Appointment 1: _____

Appointment 2: _____

Current Medication(s):

Informed Consent: *Please read and sign.*

My signature below indicates that:

- I have voluntarily chosen to receive the vaccination and consent to the administration.
- I am of legal age and authorized to execute this consent form or I am the parent/guardian of the minor patient or am authorized to consent on behalf of the client.
- I have read, or have had read to me, the Vaccine Information Statement(s) ("VIS") or Emergency Use Authorization("EUA") provided for the vaccine(s) to be administered.
- I have had the opportunity to ask questions, and all my questions have been answered to my satisfaction.
- I understand the benefits and risks of the vaccine(s).
- I will immediately alert the provider of any medical conditions which may adversely affect my personal health or effectiveness of the vaccine.
- I understand I should remain in the area for 15 minutes after the vaccination for observation or 30 minutes if I have any history of severe allergic reaction or anaphylaxis.

Participant/Guardian/Authorized Representative Signature

Date

OFFICE USE ONLY

	1 st /2 nd Dose	VFC/AVAP	Admin Site	Lot #	Manufacturer	EUA Fact Sheet Date
Pfizer-BioNTech COVID-19 Vaccine 0.3 mL		V07			PFR	
Pfizer-BioNTech COVID-19 Vaccine 0.3 mL						

	Dose #1	Dose #2
Administrator Name (printed)		
Administrator Signature		

Adverse Event Dose #1? **No** **Yes – see adverse effect flow sheet*****Adverse Event Type:** **Local** **Syncope** **Anaphylaxis*****(if there was an adverse event, an event type must be selected)**

Arrival Time : _____

Vaccine Administration Time : _____

Exit Time: _____

Administration Site	
Left Deltoid IM	LDI
Right Deltoid IM	RDI

Adverse Event Dose #2? **No** **Yes – see adverse effect flow sheet*****Adverse Event Type:** **Local** **Syncope** **Anaphylaxis*****(if there was an adverse event, an event type must be selected)**

Arrival Time: _____

Vaccine Administration Time: _____

Exit Time: _____

Administration Site	
Left Deltoid IM	LDI
Right Deltoid IM	RDI

Elizabeth deSchweinitz, MD, Dwayne Trujillo, MD, Candace Carson-McCollum, ANP

Please note that each provider is a separate entity

9500 Independence Dr., Suite 700 Anchorage, Alaska 99507

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

This Notice of Privacy Practices is NOT an authorization. This Notice of Privacy Practices describes how we, our Business Associates and their subcontractors, may use and disclose your protected health information (PHI) to carry out treatment, payment or health care operations (TPO) and for other purposes that are permitted or required by law. It also describes your rights to access and control your protected health information. "Protected health information" is information about you, including demographic information, that may identify you and that relates to your past, present or future physical or mental health condition and related health care services.

USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION

Your protected health information may be used and disclosed by your physician, our office staff and others outside of our office that are involved in your care and treatment for the purpose of providing health care services to you, to pay your health care bills, to support the operation of the physician's practice, and any other use required by law.

Treatment: We will use and disclose your protected health information to provide, coordinate, or manage your health care and any related services. This includes the coordination or management of your health care with a third party. For example, your protected health information may be provided to a physician to whom you have been referred, DME vendors, surgery centers/hospitals, referring physicians, family practitioner, physical therapists, home health providers, laboratories, worker comp adjusters and nurse case managers, etc. to ensure that the healthcare provider has the necessary information to diagnose or treat you.

Payment: Your protected health information will be used, as needed, to obtain payment for your health care services. For example, obtaining approval for a hospital stay, surgery, MRI or other diagnostic test, injection procedures, injection series, physical therapy, etc., may require that your relevant protected health information be disclosed to the health plan to obtain approval for the procedure.

Healthcare Operations: We may use or disclose, as-needed, your protected health information in order to support the business activities of your physician's practice. These activities include, but are not limited to, quality assessment, employee review, training of medical students, licensing, fundraising, and conducting or arranging for other business activities. For example, we may disclose your protected health information to medical school students that see patients at our office. In addition, we may use a sign-in sheet at the registration desk where you will be asked to sign your name and indicate your physician. We may also call you by name in the waiting room when your physician is ready to see you. We may use or disclose your protected health information, as necessary, to contact you to remind you of your appointment, and inform you about treatment alternatives or other health-related benefits and services that may be of interest to you. If we use or disclose your protected health information for fundraising activities, we will provide you the choice to opt out of those activities. You may also choose to opt back in. We may use or disclose your protected health information in the following situations without your authorization. These situations include: as required by law, public health issues as required by law, communicable diseases, health oversight, abuse or neglect, food and drug administration requirements, legal proceedings, law enforcement, coroners, funeral directors, organ donation, research, criminal activity, military activity and national security, workers' compensation, inmates, and other required uses and disclosures. Under the law, we must make disclosures to you upon your request. Under the law, we must also disclose your protected health information when required by the Secretary of the Department of Health and Human Services to investigate or determine our compliance with the requirements under Section 164.500.

USES AND DISCLOSURES THAT REQUIRE YOUR AUTHORIZATION

Other Permitted and Required Uses and Disclosures will be made **only with your consent, authorization** or opportunity to object unless required by law. Without your authorization, we are expressly prohibited to use or disclose your protected health information for marketing purposes. *(continued on back page)*

We may not sell your protected health information without your authorization. We may not use or disclose most psychotherapy notes

contained in your protected health information. We will not use or disclose any of your protected health information that contains genetic information that will be used for underwriting purposes.

You may revoke the authorization, at any time, in writing, except to the extent that your physician or the physician's practice has taken an action in reliance on the use or disclosure indicated in the authorization.

YOUR RIGHTS

The following are statements of your rights with respect to your protected health information.

You have the right to inspect and copy your protected health information (fees may apply) – Pursuant to your written request, you have the right to inspect or copy your protected health information whether in paper or electronic format. Under federal law, however, you may not inspect or copy the following records: Psychotherapy notes, information compiled in reasonable anticipation of, or used in, a civil, criminal, or administrative action or proceeding, protected health information restricted by law, information that is related to medical research in which you have agreed to participate, information whose disclosure may result in harm or injury to you or to another person, or information that was obtained under a promise of confidentiality.

You have the right to request a restriction of your protected health information – This means you may ask us not to use or disclose any part of your protected health information for the purposes of treatment, payment or healthcare operations. You may also request that any part of your protected health information not be disclosed to family members or friends who may be involved in your care or for notification purposes as described in this Notice of Privacy Practices. Your request must state the specific restriction requested and to whom you want the restriction to apply. Your physician is not required to agree to your requested restriction except if you request that the physician not disclose protected health information to your health plan with respect to healthcare for which you have paid in full out of pocket.

You have the right to request to receive confidential communications – You have the right to request confidential communication from us by alternative means or at an alternative location. You have the right to obtain a paper copy of this notice from us, upon request, even if you have agreed to accept this notice alternatively i.e. electronically.

You have the right to request an amendment to your protected health information – If we deny your request for amendment, you have the right to file a statement of disagreement with us and we may prepare a rebuttal to your statement and will provide you with a copy of any such rebuttal.

You have the right to receive an accounting of certain disclosures – You have the right to receive an accounting of disclosures, paper or electronic, except for disclosures: pursuant to an authorization, for purposes of treatment, payment, healthcare operations; required by law, that occurred prior to April 14, 2003, or six years prior to the date of the request.

You have the right to receive notice of a breach – We will notify you if your unsecured protected health information has been breached.

You have the right to obtain a paper copy of this notice from us even if you have agreed to receive the notice electronically. We reserve the right to change the terms of this notice and we will notify you of such changes on the following appointment. We will also make available copies of our new notice if you wish to obtain one.

COMPLAINTS

You may complain to us or to the Secretary of Health and Human Services if you believe your privacy rights have been violated by us. You may file a complaint with us by notifying our HIPAA Compliance Officer of your complaint. **We will not retaliate against you for filing a complaint.** HIPAA COMPLIANCE OFFICER:

Crystal Cornejo | E-mail: practicemanager@askdocs.com

We are required by law to maintain the privacy of, and provide individuals with, this notice of our legal duties and privacy practices with respect to protected health information. We are also required to abide by the terms of the notice currently in effect. If you have any questions in reference to this form, please ask to speak with our HIPAA Compliance Officer in person or by phone at our main phone number.

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 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. 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 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

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.

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

BIONTECH

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

LAB-1451-2.0

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