

INFORMED CONSENT PFIZER-BIONTECH
FDA-APPROVED (COMIRNATY) COVID-19 Vaccine

Introduction

The following is an informed consent document. Please read it carefully. It does not take the place of a conversation with the doctor regarding this proposed treatment. This document is intended to provide information that a patient should have in order to make an informed decision about a particular medical procedure, in this case whether or not to have the COVID-19 vaccine.

Purpose

The purpose of a COVID-19 vaccination is to try and prevent acquiring a COVID-19 infection by immunization with an inactivated coronavirus vaccine.

Despite extensive research and safety data, vaccines are not 100% guaranteed to be safe or effective. Agreeing to have a vaccine means that you accept the very small risk of vaccine related consequences as well as the risk of acquiring COVID despite having been vaccinated.

The purpose of this form is to explain what those risks are so that you understand them. A patient should not agree to undergo any medical treatment unless and until they understand the possible risks, benefits, alternatives, and the reason for having the treatment done.

The Vaccine

This consent is for the Pfizer COVID-19 vaccine. All of the relevant information about this vaccine, its mechanism of action, risks, and side effects is in the document entitled "VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT COMIRNATY (COVID-19 VACCINE, mRNA) AND PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) dated 9.22.21" which is provided as a separate handout. Please review this information.

Pregnant and Lactating Patients

Our providers support receiving the vaccine even if you are pregnant, trying to become pregnant or are lactating. We feel that the risks from a COVID infection exceed the possible risks of the vaccine. Please see our website for more information. Many national women's health organizations, such as Center for Disease Control (CDC), and American College of Ob/Gyn (ACOG), agree with this recommendation.

Alternatives

The current COVID-19 vaccine alternatives include the Moderna version and the J&J Janssen version.

Booster Dose

As of 9/24/21, the CDC has approved the Pfizer-BioNTech COVID-19 vaccine for one booster dose for specific populations. The dose must be 6 months or more from the 2nd Pfizer vaccine dose of the original series. The booster is approved for the following people:

- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

Agreement and Consent

To make sure that you fully understand the information contained in this Informed Consent, your physician is available to discuss the information with you after you have had a chance to read it, and before you decide whether to have the above vaccine administered. If you have questions, you are encouraged and expected to ask them, and your physician and her/his staff will be available to discuss these with you.

Your signature on this informed consent indicates:

- A. That you have read and understood the information provided in this form.
- B. That you have read and understood the information provided in the Pfizer-BioNTech COVID-19 Vaccine Information Statement (VIS).
- C. That you have been verbally informed about the COVID-19 vaccine.
- D. That you have had a chance to ask questions.
- E. That you have received all the information you want concerning this treatment.
- F. That you authorize and consent to receiving a Pfizer COVID-19 vaccine.

DATE: _____ TIME: _____

NAME: _____ SIGNATURE: _____

If signed by other than patient, indicate relationship: _____

PHYSICIAN'S STATEMENT:

The undersigned physician hereby certifies that s/he discussed the following procedure(s) with the patient and provided a full explanation of the indications for the vaccine, the benefits of getting the vaccine, the risks of the vaccine (common and remote, minor and serious), and the alternatives.

The undersigned physician further certified the patient was encouraged to ask questions, and that all of her questions were answered. The patient has agreed to receive the COVID-19 vaccine.

DATE: _____ TIME: _____

DR NAME: _____ SIGNATURE: _____