



**COVID-19 PEDIATRIC VACCINATION
INFORMED CONSENT FORM AND ASSENT FORM
FOR THE PFIZER-BIONTECH COVID-19 VACCINE**
*of the Philippine National COVID-19 Vaccine Deployment and
Vaccination Program*

Name of Minor:	Birthdate:	Sex:
Address:		
Name of Parent/Guardian:	Relationship:	
Contact Number:		
Vaccination Site:		

Section 1: Information on the risks and benefits of the Pfizer- BioNTech COVID-19 Vaccine

The Pfizer-BioNTech COVID-19 Vaccine may prevent the person vaccinated from getting severe COVID-19 infection and hospitalization. The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 12 years of age and older under an Emergency Use Authorization (EUA). The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle of the upper arm.

Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include injection site pain, injection site redness and injection site swelling, tiredness, headache, muscle pain, chills, joint pain, fever, nausea, vomiting, diarrhea, feeling unwell, and swollen lymph nodes. Some of these side effects were slightly more frequent in adolescents 12 to 15 years old. There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause temporary one-sided facial drooping and/or severe allergic reaction. Signs of a severe allergic reaction can include difficulty breathing, swelling of the face and throat, a fast heartbeat, and/or a bad rash all over the body. 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, a vaccination provider may ask the person receiving the vaccine to stay at the place where they received their vaccine for monitoring after vaccination.

The United States Center for Disease Control and Prevention (US CDC) and its partners are actively monitoring reports of myocarditis and pericarditis after COVID-19 vaccination.

Myocarditis is the inflammation of the heart muscle, and pericarditis is the inflammation of the outer lining of the heart. In both cases, the body's immune system causes

inflammation in response to an infection or some other triggers. Both myocarditis and pericarditis have the following symptoms: chest pain, shortness of breath, feelings of having a fast-beating, fluttering, or pounding heart. Cases of myocarditis reported to the US Vaccine Adverse Event Reporting System (VAERS) have occurred after mRNA COVID-19 vaccination, especially in male adolescents and young adults, more often after the second dose usually within several days after vaccination. Most patients with myocarditis or pericarditis who received care responded well to medicine and rest and felt better quickly.

Despite the side effects, recent studies show that the COVID-19 vaccination with Pfizer-BioNTech benefits far outweigh the risks.

Section 2: Parent's/Guardian's Consent for Minor's Vaccination

I confirm that I have been provided with and have read the Pfizer-BioNTech COVID-19 vaccine and Emergency Use Authorization (EUA) Information Sheet and the same has been explained to me. The Philippine FDA has authorized the use of the Pfizer-BioNTech COVID-19 vaccine under an EUA since the gathering of scientific evidence for the approval of the said vaccine and any other COVID-19 vaccine is still ongoing.

I confirm that the minor has been screened for conditions that may merit deferment or special precautions during vaccination as indicated in the Health Screening Questionnaire.

I have received sufficient information on the benefits and risks of COVID-19 vaccines and I understand the possible risks if the minor is not vaccinated.

I was provided an opportunity to ask questions, all of which were adequately and clearly answered. I, therefore, voluntarily release the Government of the Philippines, the

vaccine manufacturer, their agents and employees, as well as the hospital, the medical doctors and vaccinators, from all claims relating to the results of the use and administration of, or the ineffectiveness of the Pfizer BioNTech COVID-19 vaccine.

I understand that while most side effects are minor and resolve on their own, there is a small risk of severe adverse reactions, such as, but not limited to allergies, and that should prompt medical attention be needed, referral to the nearest hospital shall be provided immediately by the Government of the Philippines. I have been given contact information for follow up for any symptoms which may be experienced after vaccination.

I understand that by signing this Form, the minor has a right to health benefit packages under the Philippine Health Insurance Corporation (PhilHealth), in case he/she suffers a severe and/or serious adverse event, which is found to be associated with the Pfizer BioNTech COVID-19 vaccine or its administration. I understand that the right to claim compensation is subject to the guidelines of PhilHealth.

I authorize releasing all information needed for public health purposes including reporting to applicable national vaccine registries, consistent with personal and health information storage protocols of the Data Privacy Act of 2012.

Nonetheless, I understand that despite such authorization and consent given by me to release all personal and sensitive information for public health purposes, I remain entitled to the rights afforded to a Data Subject under the Data Privacy Act of 2012.

I have reviewed the information on risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine in Section 1 above and understand its risks and benefits. In providing my consent below, I confirm that I have the legal authority to give consent for the vaccination of the minor named above with the Pfizer-BioNTech COVID-19 Vaccine:

I hereby give consent to the vaccination of the minor named above with the Pfizer-BioNTech COVID-19 vaccine. I affirm that I have understood and reviewed the information included in Section 1 herein. (If this consent is not signed, dated and returned, the minor will not be vaccinated).

Signature over Printed Name of the Parent/Guardian

Date

If you choose not to have your child/ward vaccinated, please list down the reason/s:

Section 3: Minor’s Assent for Vaccination

I ACKNOWLEDGE THAT:

I am being asked to decide if I _____
(Minor’s Name) / _____ (Age) want to be vaccinated with Pfizer-BioNTech COVID-19 vaccine.

I have understood the information about the Pfizer-BioNTech COVID-19 vaccine which will be vaccinated to me, and I confirm that I have understood the same.

I asked several questions about the Pfizer-BioNTech COVID-19 vaccine and got answers to the same. I understand that I can ask questions and raise concern about COVID-19 vaccination anytime.

I understand the risk of the administration of the vaccine including the outcomes (that while most side effects are minor and resolve on their own, there can be a risk for adverse reactions in rare circumstances.)

I know that I can stop at any time in the process of vaccination without anyone reprimanding me. The attending physician will still take care of me.

I want to receive the COVID-19 vaccine at this time.

(In case the minor is not capable of giving assent due to neurological comorbidities and moderate to severe intellectual impairment, the parent or the authorized parental substitute can sign on his/her behalf.)

Signature over Printed Name of the Minor (12-17 years with comorbidities)

Date

References:
1. Pfizer-BioNTech COVID-19 Vaccine Consent Form for Individuals 12-17 Years of Age. Retrieved from: <https://www.mass.gov/doc/ma-consent-form-for-individuals-under-18-years-of-age-english-5122021/download>
2. US CDC. September 8, 2021. Myocarditis and Pericarditis After mRNA COVID-19 Vaccination. Retrieved from: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html>