



Boston Children's Health Physicians New York & Connecticut

COVID-19 Vaccine Informed Consent Form- Pfizer

Background

The U.S. Food and Drug Administration ("FDA") has approved Pfizer-BioIntech COVID-19 vaccine for children five (5) years and older with at least one (1) underlying condition that puts them at high risk for severe outcomes from COVID-19.

The American Academy of Pediatrics ("AAP") strongly recommends immunizations as the safest and most cost-effective way of preventing disease, disability and death. The AAP recommends the COVID-19 vaccine for:

- all children 6 months through 23 months,
- any child who has never received a COVID-19 vaccine,
- any child who has a condition which puts them at higher risk of severe disease or a household member who has a condition which puts them at higher risk of severe disease, or who lives in a congregate setting, and,
- any other child whose parent wishes them to receive a dose of the COVID-19 vaccine

Children five (5) years to eighteen (18) years of age and adults (with or without an underlying condition) can receive the Pfizer vaccine through a shared clinical decision-making process between a healthcare provider and the patient or parent/guardian.

Shared clinical decision-making recommendations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian. You are being provided this form to memorialize your consent to administration of the COVID-19 vaccine to your child as a result of the shared clinical-decision making process as informed by your healthcare provider's clinical judgement.

Purpose and Benefits of COVID-19 Vaccination

COVID-19 vaccine can prevent **COVID-19** disease. Vaccination can help reduce the severity of COVID-19 disease if you get sick.

COVID-19 is caused by a coronavirus called SARS-CoV-2 that spreads easily from person to person. COVID-19 can be mild to moderate, lasting only a few days, or it can be severe, requiring hospitalization, intensive care, or a ventilator to help with breathing. COVID-19 can also result in death.

COVID-19 symptoms may appear 2 to 14 days after exposure to the virus. A person can have mild, moderate, or severe symptoms.

- Symptoms can include fever; chills; cough; shortness of breath or difficulty breathing; fatigue (tiredness); muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea; vomiting; and diarrhea.

- More serious symptoms can include trouble breathing; persistent pain or pressure in the chest; new confusion; inability to wake or stay awake; and pale, gray, or blue-colored skin, lips, or nail beds (depending on skin tone).

Older adults and people of any age with certain underlying medical conditions (like heart or lung disease or diabetes) are more likely to get very sick with COVID-19.

After COVID-19 illness, some people get Long COVID, a chronic condition with symptoms lasting 3 months or longer. Symptoms of Long COVID may get better, get worse, or stay the same.

People who are up to date with COVID-19 vaccination have a lower risk of severe illness, hospitalization, and death from COVID-19 than people who are not up to date. COVID-19 vaccination is the best way to prevent Long COVID.

Getting a COVID-19 vaccine helps the body learn how to defend itself from the disease and reduces the risk for severe illness and complications. Additionally, COVID-19 vaccines can offer added protection to people who have already had COVID-19, including protection against being hospitalized if they become infected with COVID-19 again.

Potential Risks

- Pain, swelling, and redness where the shot is given, fever, tiredness (fatigue), headache, chills, muscle pain, joint pain, nausea, vomiting, and swollen lymph nodes can happen after COVID-19 vaccination.
- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have been seen rarely after COVID-19 vaccination. These risks have been observed most frequently in adolescent and young adult males. The chance of this occurring is low.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

As with any medicine, there is a very remote chance of a vaccine causing a severe allergic reaction, other serious injury, or death.

Financial Responsibility / Insurance Coverage

- Under the Affordable Care Act, vaccines with CDC recommendations for shared clinical decision-making are required to be covered at-no cost when adopted and listed on the CDC immunization schedules. Further, because the FDA has limited its approval of the pfizer COVID-19 vaccine to the individuals in the age groups and categories specified in the “Background” section above, some insurance companies **may not cover the cost** of the vaccine administration.
 - If coverage is denied, the parent/guardian may be responsible for payment.
 - It is recommended that you contact your insurance provider to ask about coverage for this service before proceeding.
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Alternatives

- Not receiving the COVID-19 vaccine at this time.
 - Using other preventive measures (masking, hygiene, avoiding high-risk exposures).
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Acknowledgment

After consultation with my healthcare provider, I acknowledge:

- I have had the opportunity to ask questions about the COVID-19 vaccine for my child.
- I understand that the FDA has not approved the COVID-19 vaccine for children under the age of eighteen (18) that are not considered high-risk or do not have an underlying condition.
- I understand the known and potential risks and benefits.
- I understand that no guarantees have been made about outcomes.
- I understand that my insurance company **may deny coverage** for this vaccine and therefore that I may be financially responsible for the cost.
- I have engaged in the shared clinical decision-making process and voluntarily consent to the administration of the COVID-19 vaccine to my child.

Patient Name: _____

Parent/Guardian Name (if applicable): _____

Signature (of patient or authorized representative of patient): _____

Date: _____

Provider Statement

I have explained the information above, answered questions, and believe that the parent/guardian understands the risks, benefits, alternatives, and potential insurance/financial implications.

Provider Name: _____

Signature: _____

Date: _____