

Informed Consent – COVID-19 Vaccination for under 16

Your child(ren) is (are) being offered a vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2 (hereinafter, the “COVID-19 Vaccine”).

This informed consent document, along with the “Fact Sheet for Recipients and Caregivers” (available at <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-coivd-19-vaccine#additional>), contains information intended to help you understand the potential risks and benefits associated with receiving the COVID-19 Vaccine.

The COVID-19 Vaccine may prevent your child from getting COVID-19. The U.S. Food and Drug Administration (FDA) has not approved a vaccine to prevent COVID-19 in children under 16. However, the FDA has authorized the emergency use of the **Pfizer-BioNTech** COVID-19 Vaccine to prevent COVID-19 in individuals 5 to 15 years of age under an Emergency Use Authorization (EUA). The COVID-19 Vaccine is administered by a licensed health provider under contract with the Commonwealth of Massachusetts (or its designee) as a 2-dose series, 3 weeks apart, into the muscle.

The COVID-19 Vaccine may not protect everyone. Side effects that have been reported with the COVID-19 Vaccine include injection site pain, tiredness, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, feeling unwell, and swollen lymph nodes. There is a remote chance that the 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 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, and/or a bad rash all over your body.

In signing this form, I agree that:

1. I have reviewed this informed consent, as well as the “Fact Sheet for Recipients and Caregivers,” which includes more detailed information about the potential risks and benefits of the COVID-19 Vaccine.
2. I have the legal authority to consent to have my child vaccinated with the COVID-19 Vaccine.
3. I understand that while precautions will be taken for my child’s safety, neither Mass General Brigham nor any of their respective trustees, officers, employees, or organization sponsors are liable for any accident or injuries that may occur to me (or my child), as a result of agreeing to receive the COVID-19 Vaccine.
4. I understand that agreeing to receive the COVID-19 Vaccine is optional, and that I can refuse to give this authorization.
5. I give permission for my insurance company to be billed for the costs of administering the COVID-19 Vaccine. The government is paying for the COVID-19 Vaccine itself, and I will not be billed for that portion of the cost of my immunization.
6. I understand that as required by state law, all immunizations will be reported to the Department of Public Health Massachusetts Immunization Information System (MIIS). I can access the MIIS Factsheet for Parents and Patients, at www.mass.gov/dph/miis, for information on the MIIS and what to do if I object to my or my family’s data being shared with other providers in the MIIS.

I, the undersigned, have reviewed the information referenced above, including information regarding the possible benefits and risks of the COVID-19 Vaccine. I may receive a copy of this consent upon request. I have been given the opportunity to ask questions before I sign this document, and I have been told that I can ask additional questions at any time.

I consent to having my child receive the COVID-19 Vaccine.

Signature of Patient (or Parent/Guardian, if applicable):
Printed Name of Parent/Guardian (if applicable):
Relationship to Patient (if applicable):
Date: