STUDENT Vaccination Consent Form

(PLEASE PRINT LEGIBLY IN CAPTIAL LETTERS USING BLACK OR BLUE INK)

Student's Last Name | Student's First Name | M.I. | Student's Date of Birth (M M / D D / Y Y)

Student's Address

City | State | Zip Code | Student's Gender

Parent/Guardian Home Phone ( )	Parent/Guardian Daytime Phone ( )	Parent/Guardian Cell Phone ( )
Parent/Guardian Email Address		
School Name	**Grade (Circle one)** Kindergarten/ Pre-K 1 2 3 4 5 6 7 Other	
Student's Doctor's Name (Last)	**(First)**	

1. As noted in the Pfizer Emergency Use Authorization "Data have not yet been submitted to FDA on administration of the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines. If you are considering to have your child receive the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss the options with your child's healthcare provider."
2. I have reviewed and completed the Pre-vaccination Checklist for COVID-19 Vaccines for my child.

I have received and read the VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS 5 THROUGH 11 YEARS OF AGE, dated October 29, 2021. I understand the risks and benefits, and give consent for my child to receive the Pfizer COVID-19 vaccine. In addition, I have received information regarding the Hawaii Immunization Registry (see attached).

I affirm that I am the parent or legal guardian of the child named at the top of this form.

Parent or Legal Guardian Name(Please Print) | Parent or Legal Guardian Signature | Date (MM / DD / NY)

HAWAII IMMUNIZATION REGISTRY INFORMATION

INFORMATION CONTAINED IN THE REGISTRY

- Immunization information including but not limited to vaccine type, date of vaccine administration, vaccine administration site and route, lot number, expiration date, patient's history of vaccine preventable diseases, contraindications, precautions, adverse reactions, and/or comments regarding vaccinations.
- Personal information including but not limited to an individual's first, middle, and last name, date of birth, gender, mailing address, phone number, parent/guardian name, parent/guardian relationship to the individual, their contact information, and mother's maiden name.

CONFIDENTIALITY AND PRIVACY INFORMATION

All authorized users and the Department of Health Immunization Branch acknowledge that the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (PL 104-191 and 45 CFR Parts 160 and 164, "Standards for Privacy of Individually Identifiable Health Information") governs the use and disclosure of individually identifiable information by entities subject to the Privacy Rule. Although HIPAA standards for privacy were used as a guide to assist in the development of the Registry Confidentiality and Privacy policies, the Registry and the Department of Health Immunization Branch are not "covered entities" under HIPAA. Providers, health plans and other covered entities who are authorized users must comply with the HIPAA Privacy Rule.

Registry information will be entered by and available to authorized users for authorized purposes only. All authorized users will be required to safeguard the privacy of patient participants by protecting confidential information in the Registry in accordance with the Hawaii Immunization Registry Confidentiality and Privacy Policy, the Hawaii Immunization Registry Security Policy, as well as all applicable State and Federal Laws.

AUTHORIZED USERS

Authorized users of the Registry may include individuals and/or entities that require regular access to patient immunization and other individually identifiable health information to provide immunization services to specific patients, maintain a computerized inventory of their public and private stock of vaccines, assess immunization status to determine immunization rates, and/or ensure compliance with mandatory immunization requirements. All authorized users are required to sign a Hawaii Immunization Registry Confidentiality and Security Statement indicating that they have received a copy of the Hawaii Immunization Registry Confidentiality and Privacy Policy and the Hawaii Immunization Registry Security Policy, understand the terms, including penalties for violation of the policies, and agree to comply with the policies.

The Department of Health Immunization Branch is responsible for oversight of the Registry and therefore will be designated as an authorized user.

USES OF REGISTRY INFORMATION (AUTHORIZED PURPOSES)

Registry immunization data and other individually identifiable health information shall be utilized by authorized users for the purposes of:

- Consolidating, maintaining, and accessing computerized immunization records;
- Consolidating and maintaining vaccine inventory information;
- Determining the immunization history of individuals and delivering health care treatment accordingly;
- Generating notices for individuals who are due or overdue for immunizations and in the event of a vaccine recall;
- Staying abreast of the complex immunization schedule by utilizing registry-supplied immunization forecasting tools;
- Assessing the immunization rate of their patient population (or subsets thereof);
- Generating official immunization records (e.g. Student's Health Record);
- Ensuring compliance with mandatory immunization requirements;
- Recording the distribution of prophylactic and treatment medications administered or dispensed in preparation for and in response to a potentially catastrophic disease threat;
- Complying with Hawaii Vaccines For Children and other State-provided vaccine programs' vaccine ordering and accountability policies and procedures; and
- Other purposes determined at the discretion of the Department of Health Immunization Branch.

Registry immunization data and other individually identifiable health information shall be utilized by the Department of Health Immunization Branch for the following public health purposes including but not limited to:

- Ensuring compliance with mandatory immunization requirements;
- Performing Quality Improvement/Quality Assessment activities;
- Complying with Hawaii Vaccines For Children and other State-provided vaccine programs' vaccine ordering and accountability policies and procedures;
- Preventing and managing outbreaks of vaccine-preventable diseases and other public health emergencies;
- Producing immunization assessment reports to aid in the development of policies and strategies to improve public health;
- Managing and maintaining the Registry system; and
- Other purposes determined at the discretion of the Department of Health Immunization Branch.

AVAILABILITY OF IMMUNIZATION RECORD INFORMATION

An individual's immunization data and other individually identifiable health information in the Registry will be made available to the individual's immunization provider, the Department of Health, and other Registry authorized users for authorized purposes only.

OPT-OUT

Individuals may choose not to include their or their child's immunization data in the Registry ("opt-out"). Individuals must opt-out in writing by completing a "Hawaii Immunization Registry Opt-Out Form" which is available from the individual's immunization provider or the Department of Health Immunization Branch. The Registry will retain only core demographic information necessary to identify the individual has chosen to opt-out of the Registry. This information is necessary to enable the Registry to filter and refuse entry of immunization information for the individual. Core demographic data will be for Hawaii Department of Health use only and will be non-displaying to all other Registry authorized users. An individual's decision not to authorize the inclusion of immunization data in the Registry will not affect whether or not they receive immunizations.

REVOCATION

An individual may revoke their decision to opt-out of the Hawaii Immunization Registry at any time. Revocations must be made in writing by completing a "Hawaii Immunization Registry Reauthorization Form" obtained from the individual's immunization provider or the Department of Health Immunization Branch.

RIGHT TO INSPECT, COPY, CORRECT OR AMEND PERSONAL AND IMMUNIZATION INFORMATION

Individuals may inspect, copy, correct or amend their or their child's immunization record information via their or their child's immunization provider. For information on how to inspect, copy, correct or amend your or your child's information, please speak with your doctor.

QUESTIONS?

If you have any questions about the Registry, please speak with your doctor or visit our website at: http://health.hawaii.gov/docd/hawaii-immunization-registry/.

VACCINE INFORMATION FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) FOR USE IN INDIVIDUALS 5 THROUGH 11 YEARS OF AGE

FOR 5 THROUGH 11 YEARS OF AGE

Your child is being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.

This Vaccine Information Fact Sheet for Recipients and Caregivers comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine for use in individuals 5 through 11 years of age.[1]

The Pfizer-BioNTech COVID-19 Vaccine has received EUA from FDA to provide a two-dose primary series to individuals 5 through 11 years of age.

This Vaccine Information Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which your child may receive because there is currently a pandemic of COVID-19. Talk to your child's vaccination provider if you have questions.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOUR CHILD GETS THIS VACCINE

WHAT IS COVID-19?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. 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 leading to death. 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.

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

[1] You may receive this Vaccine Information Fact Sheet even if your child is 12 years old. Children who will turn from 11 years to 12 years of age between their first and second dose in the primary regimen may receive, for either dose, either: (1) the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in individuals 5 through 11 years of age; or (2) COMIRNATY or one of the Pfizer-BioNTech COVID-19 Vaccine formulations authorized for use in individuals 12 years of age and older.

WHAT SHOULD YOU MENTION TO YOUR CHILD'S VACCINATION PROVIDER BEFORE YOUR CHILD GETS THE VACCINE?

Tell the vaccination provider about all of your child's medical conditions, including if your child:

- has any allergies
- has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- has a fever
- has a bleeding disorder or is on a blood thinner
- is immunocompromised or is on a medicine that affects your child's immune system
- is pregnant
- is breastfeeding
- has received another COVID-19 vaccine
- has ever fainted in association with an injection

HOW IS THE VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine will be given to your child as an injection into the muscle.
The vaccine is administered as a 2-dose series, 3 weeks apart.
The vaccine may not protect everyone.

WHO SHOULD NOT GET THE VACCINE?

Your child should not get the vaccine if your child:

- 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 VACCINE?

The 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), tromethamine, tromethamine hydrochloride, sucrose, and sodium chloride.

HAS THE VACCINE BEEN USED BEFORE?

Millions of individuals 12 years of age and older have received the Pfizer-BioNTech COVID-19 Vaccine under EUA since December 11, 2020. In a clinical trial, approximately 3,100 individuals 5 through 11 years of age have received at least 1 dose of Pfizer-BioNTech COVID-19 Vaccine. In other clinical trials, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the vaccine. The vaccine that is authorized for use in children 5 through 11 years of age includes the same mRNA and lipids but different inactive ingredients compared to the vaccine that has been used under EUA in individuals 12 years of age and older and that has been studied in clinical trials. The use of the different inactive ingredients helps stabilize the vaccine under refrigerated temperatures and the formulation can be readily prepared to deliver appropriate doses to the 5 through 11 year-old population.

WHAT ARE THE BENEFITS OF THE VACCINE?

The vaccine has been shown to prevent COVID-19.

The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE VACCINE?

There is a remote chance that the 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 vaccine. For this reason, your child's vaccination provider may ask your child to stay at the place where your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of the face and throat
- A fast heartbeat
- A bad rash all over the body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received the vaccine. In most of these people, symptoms began within a few days following receipt of the second dose of vaccine. The chance of having this occur is very low. You should seek medical attention right away if your child has any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported with the vaccine include:

- severe allergic reactions
- non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- myocarditis (inflammation of the heart muscle)
- pericarditis (inflammation of the lining outside the heart)
- injection site pain
- tiredness
- headache
- muscle pain

- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)
- decreased appetite
- diarrhea
- vomiting
- arm pain
- fainting in association with injection of the vaccine

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your child's healthcare provider if your child has any side effects that bother your child 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 HAVE MY CHILD GET THE PFIZER-BIONTECH COVID-19 VACCINE?

Under the EUA, there is an option to accept or refuse receiving the vaccine. Should you decide for your child not to receive it, it will not change your child's standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDESPFIZER-BIONTECH COVID-19 VACCINE?

For children 5 through 11 years of age, there are no other COVID-19 vaccines available under Emergency Use Authorization and there are no approved COVID-19 vaccines.

CAN MY CHILD RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE AT THESAME TIME AS OTHER VACCINES?

Data have not yet been submitted to FDA on administration of the Pfizer-BioNTech COVID-19 Vaccine at the same time with other vaccines. If you are considering to have your child receive the Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss the options with your child's healthcare provider.

WHAT ABOUT PREGNANCY OR BREASTFEEDING?

If your child is pregnant or breastfeeding, discuss the options with your healthcare provider.

WILL THE VACCINE GIVE MY CHILD COVID-19?

No. The vaccine does not contain SARS-CoV-2 and cannot give your child COVID-19.

KEEP YOUR CHILD'S VACCINATION CARD

When your child gets the first dose, you will get a vaccination card to show when to return for your child's next dose(s) of the vaccine. Remember to bring the card when your child returns.

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 CHILD'S VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your child's vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that your child receives the same vaccine when your child returns for the second dose. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19VACCINE?

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or https://TIPS.HHS.GOV.

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)?

An Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An 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 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.

This EUA for the Pfizer-BioNTech COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

Manufactured by
Pfizer Inc., New York, NY 10017

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

LAB-1486-0.3

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Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 09/30/2021