What Will Happen When I Come to the Clinic?

Name of Visit	Vaccine 1 	Post Vaccination 1	Vaccine 2	Post Vaccination 2	1-Month Follow-Up Visit
Day of Visit	Day 1	2-5 Days after Vaccine 1	1-Month after Vaccine 1	2-5 Days after Vaccine 2	1-month after vaccine 2
Type of Visit	In Clinic 2 hrs*	In Clinic 1 hr*	In Clinic 2 hrs*	In Clinic 1 hr*	In Clinic 1 hr*
Health Check					
Vital Signs					
Medication Review					
Urine Pregnancy Test					
Blood Test Amount	2 tsp 	2 tsp 	2 tsp 	2 tsp 	2 tsp 
Track My Health (*symptom e-diary)					
Reimbursement	$119	$119	$119	$119	$119

- If you are unable to complete the study, you will be paid for each visit that is completed.
- ****If you experience symptoms of COVID-19, you will have either an in-person study visit, a telehealth visit, or a telephone visit with the study staff; you will take a swab from your nose to test for COVID-19.**
- *You or your child will complete an electronic diary (e-diary) to report symptoms for 7 days after each vaccine visit You will be paid an additional $5.00 for each weekly illness e-diary completion.
- *Time in clinic is approximate.

CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER

Parent Permission Form (Sub Study B)

Study Title: A Study to Evaluate Additional Dose(s) of BNT162b2 in Healthy Individuals Previously Vaccinated With BNT162b2

KEY INFORMATION:

Investigator: Robert Frenck, MD
Contact Info:
Gamble Program for Vaccine Research
513-636-7699
Industry Protocol #: C4591031
Test Article Name: BNT162 RNA-based COVID-19 Vaccines
Funding: BioNTech and Pfizer

Reason for the study:
We are asking your child to be in a research study. Taking part in this study is voluntary (your choice). There is no penalty or change to your child's regular medical care if you decide not to participate. You can choose to take part in the study now, and then change your mind later at any time without losing any benefits or medical care to which your child is entitled.

This is a research study involving both Pfizer and BioNTech. Pfizer and BioNTech are separate companies who are cooperating to perform this study. Pfizer is responsible for conducting this study. BioNTech is the regulatory sponsor of this study. Funding for this study is provided by BioNTech and Pfizer. Cincinnati Children's Hospital will be paid to conduct this study.

A new respiratory disease appeared in Wuhan, China in December 2019 and has since rapidly spread to many other countries around the world. In January 2020, the cause of this disease was found to be a new Coronavirus; and the disease it causes was named COVID-19 (Coronavirus disease 2019).

Companies, including BioNTech/Pfizer, developed vaccines that are very safe and effective for preventing infections with the virus. As a result, the US Food and Drug Administration (FDA) has given full approval of the BioNTech/Pfizer vaccine for people 16 years of age and above. An additional dose of vaccine, also called a booster, has emergency use authorization by the FDA for anyone 16 years of age and older. Boosters are being used to increase a person's immune response against COVID-19.

Based on the available data, the following risks have been determined to be caused by BNT162b2 vaccine: Injection site pain, injection site swelling, fatigue (tiredness), increased body temperature (fever), chills, headache, diarrhea, joint aches, muscle aches, feeling sick (nausea), throwing up (vomiting) injection site redness, enlarged lymph glands, allergic reaction (symptoms may include rash, itching, hives, and swelling of the face or lips), decreased appetite, lack of energy, sweating and night sweats, pain in arm, feeling weak or unwell, and severe allergic reaction (anaphylaxis).

While the BioNTech/Pfizer vaccine has been safe, in very rare cases (about 10 in 100,000), people may have had a side effect causing some swelling in the heart muscle. This event is called myocarditis and pericarditis. As part of this study, we will give your

child a booster dose of the BioNTech/Pfizer vaccine. Additionally, we will attempt to better understand about myocarditis after vaccination.

Although not seen to date, it cannot yet be ruled out that the study vaccine could make a later COVID-19 illness more severe.

If you decide that your child can join the study, the study team will check if your child is eligible. As part of the study, your child will receive a booster dose of the BioNTech/Pfizer vaccine. At Visit 1, half of the participants will receive the BioNTech/Pfizer vaccine and the other half will receive a placebo (salt water shot). At Visit 3, your child will receive the alternative treatment from what your child received at Visit 1. Visit 1 and Visit 3 are one month apart.

Myocarditis

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received BNT162b2. Cases have mainly been reported in males under 30 years of age and following the second vaccination, however, there have been some cases reported in older males and females as well as following the first vaccination. The chance of having this occur is very low and in most of these people, symptoms began within a few days to a week following vaccination. As a precaution, 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

Please also notify study staff, when appropriate, if your child has any of these symptoms.

While some severe cases have been reported, most cases have been associated with full resolution of symptoms in the short term, however, long-term follow-up is limited. It is not known whether the risk of myocarditis or pericarditis is increased following additional doses of the vaccine, e.g. following a booster dose.

If your child has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart) previously, please tell your child´s study doctor as your child may need to come in for an assessment.

There will be about 1500 people taking part in this study in the United States and other countries. If you decide that you want your child to be in this research study, and sign this consent form, your child will be in this study for about 2 months.

This study will use competitive enrollment. This means that when a certain number of people have enrolled in the study from all study sites combined, no one else will be allowed to participate. So, it is possible that your child may not be allowed to join the study.

Your child will need to visit the research site at least 5 times including 2 vaccination visits (approximately 1 month apart), 2 post-vaccination follow-up visits (approximately 4 days after each vaccination visit), and a final visit 1-month after vaccination 2.

If your child does not meet the study requirements, your child will not be able to take part. The study doctor will explain why and discuss other options with you and your child, if available.

If your child is eligible to take part in this study and after you have signed this consent form, your child will be randomly assigned (like the flip of a coin) to Group 1 or Group 2. Group 1 receives the COVID-19 vaccine booster dose and Group 2 receives placebo (like salt water) at your child's first visit. At the second visit Group 1 receives placebo and Group 2 receives the COVID-19 vaccine booster dose. Neither you, your personal doctor and the study team will know to which group your child is assigned.

No one can choose this assignment. If urgently needed, the study doctor can find out what your child received.

The study vaccine will be given to your child only during this study and not after the study is over.

Study Procedures: A detailed study handout will be given to you.

Here's a summary of what will happen during your child's study visits:

- We will make sure your child is healthy and qualifies for the study.
- If your child qualifies, you will come to the clinic for scheduled visits 5 times.
- Your child will receive 1 dose of COVID-19 vaccine or placebo as an injection in your child's upper arm at 2 visits.
- On the days your child receives the COVID-19 vaccine or placebo, you will be asked to wait at the study site for at least 30 minutes for observation after receiving the COVID-19 vaccine or placebo.
- Your child will have blood drawn at 5 scheduled study visits.
- You will be asked to complete an electronic diary for 7 days after each vaccine appointment to report any symptoms for your child.
- You will be given a thermometer to measure your temperature and a measuring device to measure any redness or swelling at the injection site on your arm after each injection. You will be instructed how to use the devices and the electronic diary. You may receive alerts to remind you to complete the electronic diary.
- If your child has any severe symptoms after his/ her vaccination, any redness or swelling that is 21 or bigger on the measuring device, or a temperature of 39.0°C or higher, you must contact your study doctor and the study doctor or nurse may schedule an extra visit for your child.

More detailed information about the study procedures can be found under ***"(Detailed Procedures)".***

Risks to Participate:

Up until September 2021, the safety of BNT162b2 has been studied in clinical trials that have included more than 49,000 people aged over 12 years who have received at least one dose of the vaccine. Additionally, the safety of BNT162b2 has been studied in clinical trials including about 3100 children (ages 5 to <12 years) who have received at least one dose of the vaccine. Since the vaccine has been approved for emergency use or received a full or conditional marketing authorization in many countries across the world, by the end of September 2021 about 1.7 billion doses have been distributed and it is estimated that around 80% of those (around 1.3 billion doses) have been administered.

Based on the clinical trial results, and information gathered during general use, the following risks have been determined to be caused by the BNT162b2 vaccine:

Potential Side Effects of BNT162b2
Very common (occurring in more than 1 in 10 people): injection site pain, injection site swelling, fatigue (tiredness), increased body temperature (fever, more common after the second dose), chills, headache, diarrhea, joint aches, and muscle aches.
Common (between 1 in 10 and 1 in 100 people): feeling sick (nausea), being sick (vomiting), and injection site redness.
Uncommon (between 1 in 100 and 1 in 1,000 people): enlarged lymph glands, allergic reactions (symptoms may include rash, itching [not reported in adolescents], hives, and swelling of the face or lips), decreased appetite (not reported in adolescents), lethargy (not reported in children or adolescents), sweating and night sweats (not reported in children or adolescents), pain in arm, and feeling weak (not reported in children or adolescents) or unwell.
Rare (between 1 in 1,000 and 1 in 10,000 people): swelling of the face or lips (not reported in children or adolescents), myocarditis.
Frequency cannot be estimated from available data: severe allergic reaction (anaphylaxis).

The safety of an additional (third, booster) dose of BNT162b2 has also been studied in 306 people aged 18-55 years and the following risk (more frequent than listed above) has been determined to be caused by BNT162b2 vaccine following an additional third dose:

Common (between 1 in 10 and 1 in 100 people): enlarged lymph glands.

It was also determined that following an additional (third, booster) dose of BNT162b2

the following risks were not reported:

Hives, itching, lethargy, sweating and night sweats, feeling weak or unwell, swelling of the face or lips.

Myocarditis

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received BNT162b2. Cases have mainly been reported in males under 30 years of age and following the second vaccination, however, there have been some cases reported in older males and females as well as following the first vaccination. The chance of having this occur is very low and in most of these people, symptoms began within a few days to a week following vaccination. As a precaution, 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

Please also notify study staff, when appropriate, if your child has any of these symptoms.

While some severe cases have been reported, most cases have been associated with full resolution of symptoms in the short term, however, long-term follow-up is limited. It is not known whether the risk of myocarditis or pericarditis is increased following additional doses of the vaccine, e.g. following a booster dose.

If your child has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart) previously, please tell your child´s study doctor as your child may need to come in for an assessment.

As in all research studies, the COVID-19 vaccines may involve risks that might be expected based on results from studies of similar vaccines, as well as risks that are currently unknown. Therefore, it is important that you report all symptoms and side effects that your child experiences as soon as they occur, whether or not you think they are caused by the study vaccine.

Due to the way in which the study vaccines are made, they cannot cause COVID-19 disease.

If your child catches COVID-19 disease, could the vaccine make it worse?

For some other vaccines tested in animals against similar viruses (but not the coronavirus that causes COVID-19), there have been reports of the illness being more severe in the animals that received the vaccine than in those that did not. So far this has not been seen with BNT162b2. Although not seen to date, it cannot yet be ruled out that the study vaccine could make a later COVID-19 illness more severe. That is one of the reasons why you are asked to contact your study doctor if your child develops symptoms that might be caused by COVID-19 (for example, fever, cough, shortness of breath).

More detailed information about the risks of this study can be found under ***"(Detailed Risks)".***

Are there any special instructions to follow for this study?
It is important you follow all the instructions given to you by the study nurse or doctor and tell them if:

- You don't understand anything about the study
- You are not able to comply with the study requirements
- There are changes in your child's health
- The e-diary device or app is not working properly
- Your child takes any new medications or receive any other vaccines
- Your child is going away for a long period
- You/your child are going to move to a new address
- Your child wishes to take part in another research study
- Your child previously took part in this study, have been in any other study in the past 28 days, or are currently involved in any other study.
- Do not take part in any other study without approval from the study doctor. Taking part in more than one study at the same time could put your child's safety at risk.
- Take part in the study only at this location. Participating in this study at more than one study site could put your child's safety at risk.
- Tell other doctors, nurses, and health care providers about your child's participation in this study by showing the information card provided to you by the study team.
- Your child has received a COVID-19 vaccine or is taking any medication to prevent COVID-19.

Benefits to Participate:
Vaccination with BNT162b2 has been shown to be effective in preventing COVID-19 in the groups of people already studied. However, it is not known how long this protection may last. The booster may improve the level of protection. You should still follow local recommendations about how to avoid COVID-19. In addition, information learned from the research study may help other people in the future.

Other Options:
Being in this research study is completely voluntary. Instead of being in this study, you can choose for your child not to be in this study. You can also choose for your child to continue in the current study he/she is in.

Cost to Participate:
There are no costs for research tests or vaccines in this study.

Payment:
In the section below, "you" refers to the parent(s) or legally authorized representative. If you agree for your child to participate in this research study, we will pay you up to $625 for your time and effort. You or your child will receive payment for this study in the form of a reloadable debit card (Clincard). We will give you a handout that will explain how to use the card. Because you or your child are being paid for your participation, Cincinnati Children's is required by the Internal Revenue Service (IRS) to collect and use your social security number (SSN) or

taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your Social Security number. This form will be given to the Cincinnati Children's business office. It will not be kept as part of you or your child's study chart. If you move, you will need to complete another W-9 with an updated address. BioNTech/Pfizer may use information and biological samples resulting from the study to develop products or processes from which it may make a profit. There are no plans to pay you or provide you with any products developed from this study. BioNTech/Pfizer will own all products or processes that are developed using information and/or biological samples from the study.

If I have Questions or would like to know about:

- This study, a study emergency, or any research related concerns, complaints of injuries you may call Dr. Frenck, the study doctor, or the Study Nurse Coordinator at 513-636-7699 option #4.

- Your child's rights as a research participant you may call the Institutional Review Board (IRB) at 513-636-8039. The IRB is a group of scientists and community members who make sure research meets legal and ethical standards.

- You also will be given a card with important emergency contact information, including a 24-hour number. Show this card to any doctor, nurse or other health care provider if you seek emergency care while you are taking part in this study. This card includes information about the study that will help them treat you.

Detailed Procedures:

The study team will explain each visit to you and your child and give you a handout that has details about the visits. You can take the handout home with you. You and your child will be able to ask questions to make sure you understand what will happen.

These are the things that will happen to you while in the study:

Demographic Questions: Study staff will ask for personal information, such as your child's name, date of birth, race, etc.

Medical History: Study staff will ask about your child's past or present illnesses, symptoms of COVID-19, hospitalizations, surgeries and medicines your child is taking including past vaccines.

Physical Exam: We may do a brief physical exam. We will measure your child's height and weight.

Temperature: We will measure your child's oral temperature.

Blood: Staff will take blood from a vein in your child's arm or hand to see how your child is responding to the study vaccine. The schedule and amount of blood your child will have drawn is detailed in the handout.

Pregnancy Test: If your child is able to have children, we will test your child's urine before the vaccine visit.

Vaccination:
The COVID-19 vaccine (BNT162b2) will be given to your child through an injection into the muscle in your child's upper arm. Everyone will receive 2 injections. We will observe your child for 30 minutes the study agent to see if your child has any reactions to the COVID-19 vaccine (BNT162b2) .

Vaccination e-Diary:

At Visit 1, the study team will show you and your child how to fill in an electronic diary (or e-Diary). We will either give you a device (a bit like a mobile phone) or ask you to download an application ('app') to your smart phone if you have one. The device/app is secure, and your child's confidentiality will be maintained.

You will need to complete the e-diary vaccination questions every evening for 7 days after each vaccination visit. You will start on the evening of your child's vaccination visit and then complete the e-diary for 6 more days (7 days in total). It is very important that you complete the e-diary every evening as instructed. If you do not, your child's study doctor or nurse may contact you to check how your child is doing.

You will also be given a thermometer to record your child's temperature and a measuring device to measure any redness or swelling at the injection site on your child's arm after each injection. The study team will provide training on how to use the e-diary, the thermometer, and the measuring device.

If your child has any severe symptoms after his/her vaccination, any redness or swelling that is 21 or bigger on the measuring device, or a temperature of 39.0°C or higher you must contact your child's study doctor and the study doctor or nurse may schedule an extra visit.

It is very important that you and your child complete the e-Diary regularly as instructed. If you and your child do not, you will receive alerts to the device or your smartphone to remind you and your child to complete the e-Diary.

Change of Mind/Study Withdrawal:
You and your child can decide at any time to not to be in the study; it will not be held against you or your child. If this occurs, the study doctor may ask that your child comes back for a final visit so certain tests or exams can be performed to check on your child's health. The data already collected will be used as initially planned. You will be asked whether the study doctor can collect data from your child's medical care. If you agree, this data will be handled the same as research data.

You have the right to request that any remaining samples that have been collected from you as part of the study be destroyed. You may exercise this right by communicating to the study team your wish to have the samples destroyed. However, your samples may

not be able to be destroyed because they may no longer be traceable to you, may have already been used, or may have been given to a third party.

Also, the study doctor may remove your child from the study at any time. This could happen for many different reasons, for example, if there are concerns about your child's health, if you or your child do not follow study instructions, or if the study gets stopped by BioNTech/Pfizer, an institutional review board (IRB) or independent ethics committee (IEC) (a group of people who review the study to protect your rights), or by a government or regulatory agency.

If this happens, the study doctor will tell you and make sure that your child's participation in the study is stopped properly. The data and samples that have already been collected will be used as initially planned.

We will tell you about any new information that may affect your child's health, welfare, or choice to stay in the research study.

What will happen to your child's blood samples?
Your child's blood samples will be used only for scientific research. Each sample will be labeled with a code so that the laboratory workers testing the samples will not know who your child is.

Some of the samples may be stored for future testing and may be kept for up to 15 years after the study ends, at which time they will be destroyed. In addition to testing for this study, any samples left over after the study is complete may be used for additional research related to the development of products. No testing of your DNA will be performed.

You may request that your child's samples, if they can be identified, be destroyed at any time. Any data already collected from those samples will still be used for the study. The samples will remain the property of BioNTech/Pfizer and may be shared with other researchers as long as confidentiality is maintained and no testing of your child's DNA will be performed. You will not be told of additional tests, nor will you receive results of any of these tests.

Your child's specimens (even if identifiers are removed) may be used for commercial profit. Neither you, nor any other study participants, will share in this commercial profit.

Detailed Risks:

Possible risks and discomforts from study procedures

Any research has some risks, which may include negative effects that could make you unwell or uncomfortable and even potentially be serious or life-threatening. All research participants taking part in the study will be watched carefully for any negative effects; however, the study team does not know all the effects that the study vaccine may have

on your child.

There may be other risks that are currently unknown because the study drug is still being developed (or is experimental).

Allergic Reaction
Vaccines can cause severe allergic reaction. It could be minor (rashes) or more severe. Such reactions are rare and would happen within a few minutes to a few hours after the vaccine is given. Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, drop in blood pressure, and weakness. If severe allergic reactions are not treated right away, they could become serious or lead to death, but the study doctors do not expect this. There will be medicines available to treat allergic reactions.

Very rarely, people may have a nervous system reaction (for example, a seizure) after a vaccine.

Placebo Risks
Since the placebo injection contains salt-water and no active ingredients, the chances of having the side effects mentioned above are less likely. In other studies, using the same placebo, some people who received the placebo injection reported pain, bruising, swelling and redness at the site of injection.

Risks due to blood collection
Blood draws may cause pain, bruising, or redness where the needle goes into the vein. Although it is rare, some people have gotten an infection from having their blood drawn. Because some people faint during or after the blood draw, your child will be given the option of lying down to have blood drawn.

Loss of Privacy
There is a chance that unauthorized persons could see your child's study information. All attempts will be made to keep this information confidential within the limits of the law. Only people who are involved in the conduct, oversight, monitoring, or auditing of this trial will be allowed access to the PHI that is collected.

Pregnancy-Related Risks; Use of Birth Control

The effects of the COVID-19 vaccine on sperm, a pregnancy, a fetus, or a nursing child are not known.

If your child is sexually active, he/she must use birth control during the study and for at least 28 days after their last vaccination. If appropriate the study doctor will talk to you/your child about this and explain your child's options. The study doctor will also check that your child understands how to use the birth control method and may review this with your child at each of your child's research study visits. If your child wants to stop using the required birth control during the research study, you/your child should tell

the study doctor immediately. Your child may be withdrawn from the research study if they stop using birth control.

If your child is a girl, and has started to have periods, the study doctor or nurse will test her urine to make sure she is not pregnant. The study doctor or nurse will tell you the results of your child's pregnancy test.

If your daughter is pregnant, planning to become pregnant or is breast feeding a baby, she cannot be in the study as there may be risks to the unborn baby or nursing baby. Nobody knows what these risks are right now.

If you think your daughter is pregnant during the study, she or you must tell the study doctor immediately. If your daughter becomes pregnant, she will have to leave the study. The study doctor will ask for information about the pregnancy and the birth of the baby. The study doctor may share this information with others who are working on this study.

If your child is a boy, and he thinks that he may have gotten a girl pregnant, he or you must tell your child's study doctor immediately. The study doctor may ask for information about the pregnancy and the birth of the baby. The study doctor may share this information with others who are working on this study.

If your son is taking part in the study, he is not allowed to donate sperm for at least 28 days after his last vaccination.

Pregnancy Follow-up

If your child or your child's partner become pregnant during the study, up until 28 days after your child's last study injection, please tell the study staff immediately. Please also tell the staff who will be taking care of your child/your child's partner during the pregnancy that your child took part in this study. The study staff will ask if your child/your child's partner or your child's pregnancy doctor is willing to provide updates on the progress of the pregnancy and its outcome. If your child/your child's partner agree, this information will be provided to BioNTech/Pfizer for safety follow-up.

Privacy

In order to conduct the study and comply with legal and regulatory requirements, your study team will collect information about you. Information about you may include information that directly identifies you, demographics, and sensitive information such as your medical history and data from this study (including diagnoses, treatment, sex, race, and ethnicity). If required by this study, the study team may also collect biological samples from you and take images or make audio/video recordings of you.

Information may be collected from electronic devices if you use a mobile application or other digital tool during the study. You should review the main consent document as well as the terms and conditions and privacy policy of any digital tool or mobile application used in the study to understand further how information collected through those digital tools and applications may be used.

If you provide an emergency contact or details of family medical history you should inform that person or those persons you have done so and that their information will be used as described in this document.

Please note the following information regarding the use of text messages to communicate with you:

- The study team, or a company working on behalf of BioNTech/Pfizer or the study site, may send text messages to remind you to complete the eDiary, or other study-related information. Text messages will be sent only to the contact telephone number that you have provided. The number of messages may vary depending on the specific requirements of the study.
- Message and data rates may apply. Please contact your wireless phone provider to inquire about the details of your plan.
- The messages received through this program may appear on your mobile phone screen as soon as they are received, even when the phone is locked. These messages could be seen and read by others who are near your phone when the message is received.
- Text messages are not encrypted. Encryption is a way of coding a message so that only authorized people can access it. There is a risk that information contained in unencrypted text messages may not be secure and could be read, used or disclosed by people other than the study team or BioNTech/Pfizer, such as your wireless service provider or other unauthorized people.

Receiving these text messages is optional; you can still take part in the study even if you choose not to receive the text messages. Please indicate your choice within the box below. If you agree to receive text messages now, you can change your mind later. To stop receiving text messages related to this study, reply STOP to any text messages that you receive for this study. For questions regarding text messages, please contact the study team.

____ Yes, I agree that the study team (or others working on behalf of BioNTech/Pfizer or the study site) may send me text messages as described above.

____ No, I do NOT agree that the study team (or others working on behalf of BioNTech/Pfizer or the study site) may send me text messages as described above.

You may withdraw your child from the study at any time at your own request, or your child may be withdrawn at any time at the discretion of the investigator for safety, behavioral, compliance, or administrative reasons. If you decide to have your child leave the study, you will be asked why you would like to have your child withdraw.

Biological Samples

Your child must provide biological samples in order to take part in this study. These samples taken from your child may be sent to or stored in a foreign country. Additional samples may be collected depending on the results of your child's laboratory tests or if a replacement sample is needed. A company hired by BioNTech/Pfizer may be involved in the collection, transportation, or storage of these samples.

Your child's blood samples

Everyone in the study will need to give 5 blood samples. The blood samples will be approximately 10 mL of blood (about 2 teaspoons).

The blood samples will be collected from a vein in your child's arm to test your child's

antibody levels before and after your child's study vaccination(s).

Efforts will be made to limit the use and disclosure of your child's personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your child's information include the IRB and other representatives of this organization.

Your child will be registered in the Cincinnati Children's Hospital Medical Center's computer system as a research participant. A copy of this consent form will be included in your child's research chart. To keep your child's information private and confidential, Cincinnati Children's Hospital Medical Center and/or the study doctor will:

- Use code numbers instead of your child's name in your study chart
- Limit the people who can see your child's study records
- Not identify your child in any records or articles published about the study findings

Any personal information collected about your child during this study will be entered into records, including health records, maintained by the study team at your child's study site. Your child's medical records that include information that directly identifies your child may be uploaded to secure systems maintained by a third party engaged by BioNTech/Pfizer so that BioNTech/Pfizer and/or BioNTech/Pfizer representatives can review and verify study data. Some of the uploaded records will be kept for 15 years. The remaining records that are uploaded will be temporary and removed/deleted after the study is over.

To help protect your child's confidentiality, we will use study ID numbers on research data. The data will be stored in locked cabinets and/or offices when not in use. Only research team members who are involved in the conduct, oversight or auditing of this study will have access to the research data.

Electronic data will be stored in password protected computers and websites. Personnel at the central storage and testing lab will not know your child's identity or the study ID number assigned to your child for the study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

If injured while in the study:

If you believe that your child has been injured as a result of this research, you should contact the study doctor, Dr. Robert Frenck, as soon as possible to discuss the concerns. Treatment for injuries is available at Cincinnati Children's. If you go to the Emergency Room or to another hospital or doctor, it is important that you tell them that your child is in a research study. If possible, you should give them a copy of this consent form.

Cincinnati Children's follows a policy of making all decisions about compensation for the medical treatment of physical injuries that happened during or were caused by research on an individual basis.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?

Cincinnati Children's Hospital Medical Center (Cincinnati Children's) will need to use and share your PHI as part of this study. This PHI will come from:

- Your child's medical records
- Your child's research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Who will share, receive and/or use your protected health information in this study?

- Staff at all the research study sites (including Cincinnati Children's)
- Personnel who provide services to your child as part of this study
- Other individuals and organizations that need to use your child's PHI in connection with the research, including people at BioNTech/Pfizer and organizations that BioNTech/Pfizer may use to oversee or conduct the study.
- The Food and Drug Administration or similar agencies in other countries
- The members of the Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?

People that receive your child's PHI as part of the research are generally limited in how they can use your child's PHI. In addition, most people who receive your child's PHI are also required by federal privacy laws to protect your child's PHI. However, some people that may receive your child's PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

As mentioned above, information about your child that is sent outside the research site, including samples, will be assigned a numerical code. This code replaces your child's name when sending information and samples to the BioNTech/Pfizer or other recipients. BioNTech/Pfizer will use your child's coded information, including samples, to learn more about the study vaccine and viruses. BioNTech/Pfizer may also use your child's coded information and samples to design and conduct research in order to gain a further understanding of other diseases and to advance science, including development of other medicines for patients. BioNTech/Pfizer may share your child's coded information and samples with researchers and organizations collaborating with and providing services to BioNTech/Pfizer.

Can you change your mind?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your child's PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI, you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?

Your permission for the study site to disclose your information does not expire unless you withdraw your permission.

Will your other medical care be impacted?

By signing this document, you agree for your child to participate in this research study and give permission to Cincinnati Children's to use and share your child's PHI for the purpose of this research study. If you refuse to sign this document, your child will not be able to participate in the study. However, your rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether your child should participate in this research, you will document your permission by signature below. You will receive a copy of this signed document for your records.

_____
Printed Name of Research Participant

Signature of Parent or Legal Guardian	Date

* If signed by a legally authorized representative, a description of such representative's authority must be provided

Signature of Individual Obtaining Consent	Date

CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER

Informed Consent Form (Sub Study B)

Study Title: A Study to Evaluate Additional Dose(s) of BNT162b2 in Healthy Individuals Previously Vaccinated With BNT162b2

KEY INFORMATION:

Investigator: Robert Frenck, MD
Contact Info:
Gamble Program for Vaccine Research
513-636-7699
Industry Protocol #: C4591031
Test Article Name: BNT162 RNA-based COVID-19 Vaccines
Funding: BioNTech and Pfizer Inc.

Reason for the study:

We are asking you to be in a research study. Taking part in **this study is** voluntary (your choice). There is no penalty or change **to your** regular medical care if you decide not to participate. **You can choose to take part in the study now, and then change your mind later at any time** without losing any benefits or medical care to which you are entitled.

This is a research study involving both Pfizer and BioNTech. Pfizer and BioNTech are separate companies who are cooperating to perform this study. Pfizer is responsible for conducting this study. BioNTech is the regulatory sponsor of this study. Funding for this study is provided by BioNTech and Pfizer. Cincinnati Children's Hospital will be paid to conduct this study.

A new respiratory disease appeared in Wuhan, China in December 2019 and has since rapidly spread to many other countries around the world. In January 2020, the cause of this disease was found to be a new Coronavirus; and the disease it causes was named COVID-19 (Coronavirus disease 2019).

Companies, including BioNTech/Pfizer, developed vaccines that are very safe and effective for preventing infections with the virus. As a result, the US Food and Drug Administration (FDA) has given full approval of the BioNTech/Pfizer vaccine for people 16 years of age and above. An additional dose of vaccine, also called a booster, has emergency use authorization by the FDA for anyone 16 years of age and older. Boosters are being used to increase a person's immune response against COVID-19.

Based on the available data, the following risks have been determined to be caused by BNT162b2 vaccine: Injection site pain, injection site swelling, fatigue (tiredness), increased body temperature (fever), chills, headache, diarrhea, joint aches, muscle aches, feeling sick (nausea), throwing up (vomiting) injection site redness, enlarged lymph glands, allergic reaction (symptoms may include rash, itching, hives, and swelling of the face or lips), decreased appetite, lack of energy, sweating and night sweats, pain in arm, feeling weak or unwell, and severe allergic reaction (anaphylaxis).

While the BioNTech/Pfizer vaccine has been safe, in very rare cases (about 10 in 100,000), people may have had a side effect causing some swelling in the heart muscle. This event is called myocarditis and pericarditis. As part of this study, we will give you a

booster dose of the BioNTech/Pfizer vaccine. Additionally, we will attempt to better understand about myocarditis after vaccination.

Although not seen to date, it cannot yet be ruled out that the study vaccine could make a later COVID-19 illness more severe.

If you decide that you want to join the study, the study team will check if you are eligible. As part of the study, you will receive a booster dose of the BioNTech/Pfizer vaccine. At Visit 1, half of the participants will receive the BioNTech/Pfizer vaccine and the other half will receive a placebo (salt water shot). At Visit 3, you will receive the alternative treatment from what you received at Visit 1. Visit 1 and Visit 3 are one month apart.

Myocarditis

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received BNT162b2. Cases have mainly been reported in males under 30 years of age and following the second vaccination, however, there have been some cases reported in older males and females as well as following the first vaccination. The chance of having this occur is very low and in most of these people, symptoms began within a few days to a week following vaccination. As a precaution, you should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

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

Please also notify study staff, when appropriate, if you have any of these symptoms.

While some severe cases have been reported, most cases have been associated with full resolution of symptoms in the short term, however, long-term follow-up is limited. It is not known whether the risk of myocarditis or pericarditis is increased following additional doses of the vaccine, e.g. following a booster dose.

If you have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart) previously, please tell your study doctor as you may need to come in for an assessment.

There will be about 1500 people taking part in this study in the United States and other countries. If you decide that you want to be in this research study, and sign this consent form, you will be in this study for about 2 months.

This study will use competitive enrollment. This means that when a certain number of people have enrolled in the study from all study sites combined, no one else will be allowed to participate. So, it is possible that you may not be allowed to join the study

You will need to visit the research site at least 5 times including 2 vaccination visits (approximately 1 month apart), 2 post-vaccination follow-up visits (approximately 4 days after each vaccination visit), and a final visit 1-month after vaccination 2.

If you do not meet the study requirements, you will not be able to take part. The study doctor will explain why and discuss other options with you, if available.

If you are eligible to take part in this study and after you have signed this consent form, you will be randomly assigned (like the flip of a coin) to Group 1 or Group 2. Group 1 receives the COVID-19 vaccine booster dose and Group 2 receives placebo (like salt water) at your first visit. At the second visit Group 1 receives placebo and Group 2 receives the COVID-19 vaccine booster dose. Neither you, your personal doctor and the study team will know to which group you are assigned.

No one can choose this assignment. If urgently needed, the study doctor can find out what you received.

The study vaccine will be given to you only during this study and not after the study is over.

Study Procedures: A detailed study handout will be given to you.

Here's a summary of what will happen during your study visits:

- We will make sure you are healthy and qualify for the study.
- If you qualify, you will come to the clinic for scheduled visits 5 times.
- You will receive 1 dose of COVID-19 vaccine or placebo as an injection in your upper arm at 2 visits.
- On the days you receive the COVID-19 vaccine or placebo, you will be asked to wait at the study site for at least 30 minutes for observation after receiving the COVID-19 vaccine or placebo.
- You will have blood drawn at 5 scheduled study visits.
- You will be asked to complete an electronic diary for 7 days after each vaccine appointment to report any symptoms.
- You will be given a thermometer to measure your temperature and a measuring device to measure any redness or swelling at the injection site on your arm after each injection. You will be instructed how to use the devices and the electronic diary. You may receive alerts to remind you to complete the electronic diary.
- If you have any severe symptoms after your vaccination, any redness or swelling that is 21 or bigger on the measuring device, or a temperature of 39.0°C or higher, you must contact your study doctor and the study doctor or nurse may schedule an extra visit for you.

More detailed information about the study procedures can be found under ***"(Detailed Procedures)".***

Risks to Participate:

Up until September 2021, the safety of BNT162b2 has been studied in clinical trials that have included more than 49,000 people aged over 12 years who have received at least one dose of the vaccine. Additionally, the safety of BNT162b2 has been studied in clinical trials including about 3100 children (ages 5 to <12 years) who have received at least one dose of the vaccine. Since the vaccine has been approved for emergency use or received a full or conditional marketing authorization in many countries across the world, by the end of September 2021 about 1.7 billion doses have been distributed and it is estimated that around 80% of those (around 1.3 billion doses) have been administered.

Based on the clinical trial results, and information gathered during general use, the following risks have been determined to be caused by the BNT162b2 vaccine:

Potential Side Effects of BNT162b2
Very common (occurring in more than 1 in 10 people): injection site pain, injection site swelling, fatigue (tiredness), increased body temperature (fever, more common after the second dose), chills, headache, diarrhea, joint aches, and muscle aches.
Common (between 1 in 10 and 1 in 100 people): feeling sick (nausea), being sick (vomiting), and injection site redness.
Uncommon (between 1 in 100 and 1 in 1,000 people): enlarged lymph glands, allergic reactions (symptoms may include rash, itching [not reported in adolescents], hives, and swelling of the face or lips), decreased appetite (not reported in adolescents), lethargy (not reported in children or adolescents), sweating and night sweats (not reported in children or adolescents), pain in arm, and feeling weak (not reported in children or adolescents) or unwell.
Rare (between 1 in 1,000 and 1 in 10,000 people): swelling of the face or lips (not reported in children or adolescents), myocarditis.
Frequency cannot be estimated from available data: severe allergic reaction (anaphylaxis).

The safety of an additional (third, booster) dose of BNT162b2 has also been studied in 306 people aged 18-55 years and the following risk (more frequent than listed above) has been determined to be caused by BNT162b2 vaccine following an additional third dose:
Common (between 1 in 10 and 1 in 100 people): enlarged lymph glands.

It was also determined that following an additional (third, booster) dose of BNT162b2 the following risks were not reported:

Hives, itching, lethargy, sweating and night sweats, feeling weak or unwell, swelling of the face or lips.

Myocarditis

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received BNT162b2. Cases have mainly been reported in males under 30 years of age and following the second vaccination, however, there have been some cases reported in older males and females as well as following the first vaccination. The chance of having this occur is very low and in most of these people, symptoms began within a few days to a week following vaccination. As a precaution, you should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

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

Please also notify study staff, when appropriate, if you have any of these symptoms.

While some severe cases have been reported, most cases have been associated with full resolution of symptoms in the short term, however, long-term follow-up is limited. It is not known whether the risk of myocarditis or pericarditis is increased following additional doses of the vaccine, e.g. following a booster dose.

If you have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart) previously, please tell your study doctor as you may need to come in for an assessment.

As in all research studies, the COVID-19 vaccines may involve risks that might be expected based on results from studies of similar vaccines, as well as risks that are currently unknown. Therefore, it is important that you report all symptoms and side effects that you experience as soon as they occur, whether or not you think they are caused by the study vaccine.

Due to the way in which the study vaccines are made, they cannot cause COVID-19 disease.

If I catch COVID-19 disease, could the vaccine make it worse?

For some other vaccines tested in animals against similar viruses (but not the coronavirus that causes COVID-19), there have been reports of the illness being more severe in the animals that received the vaccine than in those that did not. So far this has not been seen with BNT162b2. Although not seen to date, it cannot yet be ruled out that the study vaccine could make a later COVID-19 illness more severe. Contact your study doctor if you develop symptoms that might be caused by COVID-19 (for example, fever, cough, shortness of breath).

More detailed information about the risks of this study can be found under ***"(Detailed Risks)".***

Are there any special instructions to follow for this study?
It is important you follow all the instructions given to you by the study nurse or doctor and tell them if:

- You don't understand anything about the study
- You are not able to comply with the study requirements
- There are changes in your health
- Your e-diary device or app is not working properly
- You take any new medications or receive any other vaccines
- You are going away for a long period
- You are going to move to a new address
- You wish to take part in another research study
- You previously took part in this study, have been in any other study in the past 28 days, or are currently involved in any other study.
- Do not take part in any other study without approval from the study doctor. Taking part in more than one study at the same time could put your safety at risk.
- Take part in the study only at this location. Participating in this study at more than one study site could put your safety at risk.
- Tell other doctors, nurses, and health care providers about your participation in this study by showing the information card provided to you by the study team.
- You have received a COVID-19 vaccine or are taking any medication to prevent COVID-19

Benefits to Participate:

Vaccination with BNT162b2 has been shown to be effective in preventing COVID-19 in the groups of people already studied. However, it is not known how long this protection may last. The booster may improve the level of protection. You should still follow local recommendations about how to avoid COVID-19. In addition, information learned from the research study may help other people in the future.

Other Options:
Being in this research study is completely voluntary. Instead of being in this study, you can choose not to be in this study. You can also choose to continue in the current study you are in.

Cost to Participate:
There are no costs for research tests or vaccines in this study.

Payment:
If you agree to participate in this research study, we will pay you up to $625 for your time and effort. You will receive payment for this study in the form of a reloadable debit card (Clincard). We will give you a handout that will explain how to use the card. Because you are being paid for your participation, Cincinnati Children's is required by the Internal Revenue Service (IRS) to collect and use your social security number

(SSN) or taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your Social Security number. This form will be given to the Cincinnati Children's business office. It will not be kept as part of your study chart. If you move, you will need to complete another W-9 with an updated address. BioNTech/Pfizer may use information and biological samples resulting from the study to develop products or processes from which it may make a profit. There are no plans to pay you or provide you with any products developed from this study. BioNTech/Pfizer will own all products or processes that are developed using information and/or biological samples from the study.

If I have Questions or would like to know about:

- This study, a study emergency, or any research related concerns, complaints of injuries you may call Dr. Frenck, the study doctor, or the Study Nurse Coordinator at 513-636-7699 option #4.
- Your rights as a research participant you may call the Institutional Review Board (IRB) at 513-636-8039. The IRB is a group of scientists and community members who make sure research meets legal and ethical standards.
- You also will be given a card with important emergency contact information, including a 24-hour number. Show this card to any doctor, nurse or other health care provider if you seek emergency care while you are taking part in this study. This card includes information about the study that will help them treat you.

Detailed Procedures:
The study team will explain each visit to you and give you a handout that has details about the visits. You can take the handout home with you. You will be able to ask questions to make sure you understand what will happen.

These are the things that will happen to you while in the study:

Demographic Questions: Study staff will ask for personal information, such as your name, date of birth, race, etc.

Medical History: Study staff will ask about your past or present illnesses, symptoms of COVID-19, hospitalizations, surgeries and medicines you are taking including past vaccines.

Physical Exam: We may do a brief physical exam. We will measure your height and weight.

Temperature: We will measure your oral temperature.

Blood: Staff will take blood from a vein in your arm or hand to see how you are responding to the study vaccine. The schedule and amount of blood you will have drawn is detailed in the handout.

Pregnancy Test: If you are a woman and able to have children, we will test your urine at before the vaccine visit.

Vaccination:
The COVID-19 vaccine (BNT162b2) will be given to you through an injection into the muscle in your upper arm. Everyone will receive 2 injections. We will observe you for 30 minutes after giving the study agent to see if you have any reactions to the COVID-19 vaccine (BNT162b2).

Vaccination e-Diary:
At Visit 1, the study team will show you how to fill in an electronic diary (or e-Diary). We will either give you a device (a bit like a mobile phone) or ask you to download an application ('app') to your smart phone if you have one. The device/app is secure, and your confidentiality will be maintained.

You will need to complete the e-diary vaccination questions every evening for 7 days after each vaccination visit. You will start on the evening of your vaccination visit and then complete the e-diary for 6 more days (7 days in total). It is very important that you complete the e-diary every evening as instructed. If you do not, your study doctor or nurse may contact you to check how you are doing.

You will also be given a thermometer to record your temperature and a measuring device to measure any redness or swelling at the injection site on your arm after each injection. The study team will provide training on how to use the e-diary, the thermometer, and the measuring device.

If you have any severe symptoms after your vaccination, any redness or swelling that is 21 or bigger on the measuring device, or a temperature of 39.0°C or higher you must contact your study doctor and the study doctor or nurse may schedule an extra visit.

It is very important that you complete the e-Diary regularly as instructed. If you do not, you will receive alerts to the device or your smartphone to remind you to complete the e-Diary.

Change of Mind/Study Withdrawal:
You can decide at any time to not to be in the study; it will not be held against you. If this occurs, the study doctor may ask that you come back for a final visit so certain tests or exams can be performed to check on your health. The data already collected will be used as initially planned. You will be asked whether the study doctor can collect data from your medical care. If you agree, this data will be handled the same as research data.

You have the right to request that any remaining samples that have been collected from you as part of the study be destroyed. You may exercise this right by communicating to the study team your wish to have the samples destroyed. However, your samples may not be able to be destroyed because they may no longer be traceable to you, may have already been used, or may have been given to a third party.

Also, the study doctor may remove you from the study at any time. This could happen for many different reasons, for example, if there are concerns about your health, if you do not follow study instructions, or if the study gets stopped by BioNTech/Pfizer, an institutional review board (IRB) or independent ethics committee (IEC) (a group of people who review the study to protect your rights), or by a government or regulatory agency.

If this happens, the study doctor will tell you and make sure that your participation in the study is stopped properly. The data and samples that have already been collected will be used as initially planned.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research study.

What will happen to my blood samples?
Your blood samples will be used only for scientific research. Each sample will be labeled with a code so that the laboratory workers testing the samples will not know who you are.

Some of the samples may be stored for future testing and may be kept for up to 15 years after the study ends, at which time they will be destroyed. In addition to testing for this study, any samples left over after the study is complete may be used for additional research related to the development of products. No testing of your DNA will be performed.

You may request that your samples, if they can be identified, be destroyed at any time. Any data already collected from those samples will still be used for the study. The samples will remain the property of BioNTech/Pfizer and may be shared with other researchers as long as confidentiality is maintained and no testing of your DNA will be performed.

Detailed Risks:

Possible risks and discomforts from study procedures

Any research has some risks, which may include negative effects that could make you unwell or uncomfortable and even potentially be serious or life-threatening. All research participants taking part in the study will be watched carefully for any negative effects; however, the study team does not know all the effects that the study vaccine may have

on you.

There may be other risks that are currently unknown because the study drug is still being developed (or is experimental).

Allergic Reaction
Vaccines can cause severe allergic reaction. It could be minor (rashes) or more severe. Such reactions are rare and would happen within a few minutes to a few hours after the vaccine is given. Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, drop in blood pressure, and weakness. If severe allergic reactions are not treated right away, they could become serious or lead to death, but the study doctors do not expect this. There will be medicines available to treat allergic reactions.

Very rarely, people may have a nervous system reaction (for example, a seizure) after a vaccine.

Placebo Risks
Since the placebo injection contains salt-water and no active ingredients, the chances of having the side effects mentioned above are less likely. In other studies, using the same placebo, some people who received the placebo injection reported pain, bruising, swelling and redness at the site of injection.

Risks due to blood collection
Blood draws may cause pain, bruising, or redness where the needle goes into the vein. Although it is rare, some people have gotten an infection from having their blood drawn. Because some people faint during or after the blood draw, you will be given the option of lying down when you have your blood drawn.

Loss of Privacy
There is a chance that unauthorized persons could see your study information. All attempts will be made to keep this information confidential within the limits of the law. Only people who are involved in the conduct, oversight, monitoring, or auditing of this trial will be allowed access to the Personal Health Information that is collected.

Pregnancy-Related Risks; Use of Birth Control
The effects of the COVID-19 vaccine on sperm, a pregnancy, a fetus, or a nursing child are not known.

If you are currently pregnant, plan to become pregnant, or are breastfeeding a child, you will not be allowed to join this study.

If you are able to have children and you are sexually active, you must use birth control consistently and correctly for at least 28 days after you receive your study vaccine. This applies to men as well as women who take part in the research study. The study staff will discuss with you the methods of birth control that you should use while you are in this research study and will help you select the method(s) that is appropriate for you.

The study doctor will also check that you understand how to use the birth control method and may review this with you at each of your research study visits.

Birth control methods, even when used properly are not perfect. If you or your partner becomes pregnant during the research study, or you want to stop your required birth control during the research study, you should tell the study doctor immediately. You may be withdrawn from the research study if you stop using birth control or you become pregnant.

If you are a male, you will not be allowed to donate sperm for at least 28 days after your last vaccination.

Pregnancy Follow-up

If you or your partner become pregnant during the study, up until 28 days after you last study injection, please tell the study staff immediately. Please also tell the staff who will be taking care of you/your partner during the pregnancy that you took part in this study. The study staff will ask if you/your partner or your pregnancy doctor is willing to provide updates on the progress of the pregnancy and its outcome. If you/your partner agree, this information will be provided to BioNTech/Pfizer for safety follow-up.

Privacy

In order to conduct the study and comply with legal and regulatory requirements, your study team will collect information about you. Information about you may include information that directly identifies you, demographics, and sensitive information such as your medical history and data from this study (including diagnoses, treatment, sex, race, and ethnicity). If required by this study, the study team may also collect biological samples from you and take images or make audio/video recordings of you.

Information may be collected from electronic devices if you use a mobile application or other digital tool during the study. You should review the main consent document as well as the terms and conditions and privacy policy of any digital tool or mobile application used in the study to understand further how information collected through those digital tools and applications may be used.

If you provide an emergency contact or details of family medical history you should inform that person or those persons you have done so and that their information will be used as described in this document.

Please note the following information regarding the use of text messages to communicate with you:

- The study team, or a company working on behalf of BioNTech/Pfizer or the study site, may send text messages to remind you to complete the eDiary, or other study-related information. Text messages will be sent only to the contact telephone number that you have provided. The number of messages may vary depending on the specific requirements of the study.
- Message and data rates may apply. Please contact your wireless phone provider

to inquire about the details of your plan.

- The messages received through this program may appear on your mobile phone screen as soon as they are received, even when the phone is locked. These messages could be seen and read by others who are near your phone when the message is received.

- Text messages are not encrypted. Encryption is a way of coding a message so that only authorized people can access it. There is a risk that information contained in unencrypted text messages may not be secure and could be read, used or disclosed by people other than the study team or BioNTech/Pfizer, such as your wireless service provider or other unauthorized people.

Receiving these text messages is optional; you can still take part in the study even if you choose not to receive the text messages. Please indicate your choice within the box below. If you agree to receive text messages now, you can change your mind later. To stop receiving text messages related to this study, reply STOP to any text messages that you receive for this study. For questions regarding text messages, please contact the study team.

____ Yes, I agree that the study team (or others working on behalf of BioNTech/Pfizer or the study site) may send me text messages as described above.

____ No, I do NOT agree that the study team (or others working on behalf of BioNTech/Pfizer or the study site) may send me text messages as described above.

You may withdraw from the study at any time at your own request, or you may be withdrawn at any time at the discretion of the investigator for safety, behavioral, compliance, or administrative reasons. If you decide to leave the study, you will be asked why you would like to withdraw.

Biological Samples

You must provide biological samples in order to take part in this study. These samples taken from you may be sent to or stored in a foreign country. Additional samples may be collected depending on the results of your laboratory tests or if a replacement sample is needed. A company hired by BioNTech/Pfizer may be involved in the collection, transportation, or storage of these samples.

Your blood samples

Everyone in the study will need to give 5 blood samples. The blood samples will be approximately 10 mL of blood (about 2 teaspoons).

The blood samples will be collected from a vein in your arm to test your antibody levels before and after your study vaccination(s).

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

You will be registered in the Cincinnati Children's Hospital Medical Center's computer system as a research participant. A copy of this consent form will be included in your research chart. To keep your information private and confidential, Cincinnati Children's Hospital Medical Center and/or the study doctor will:

- Use code numbers instead of your name in your study chart
- Limit the people who can see your study records
- Not identify you in any records or articles published about the study findings

Any personal information collected about you during this study will be entered into records, including health records, maintained by the study team at your study site. Your medical records that include information that directly identifies you may be uploaded to secure systems maintained by a third party engaged by BioNTech/Pfizer so that BioNTech/Pfizer and/or BioNTech/Pfizer representatives can review and verify study data. Some of the uploaded records will be kept for 15 years. The remaining records that are uploaded will be temporary and removed/deleted after the study is over.

To help protect your confidentiality, we will use study ID numbers on research data. The data will be stored in locked cabinets and/or offices when not in use. Only research team members who are involved in the conduct, oversight or auditing of this study will have access to the research data.

Electronic data will be stored in password protected computers and websites. Personnel at the central storage and testing lab will not know your identity or the study ID number assigned to you for the study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

If injured while in the study:

If you believe that you have been injured as a result of this research, you should contact the study doctor, Dr. Robert Frenck, as soon as possible to discuss the concerns. Treatment for injuries is available at Cincinnati Children's. If you go to the Emergency Room or to another hospital or doctor, it is important that you tell them that you are in a research study. If possible, you should give them a copy of this consent form.

Cincinnati Children's follows a policy of making all decisions about compensation for the medical treatment of physical injuries that happened during or were caused by research on an individual basis.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?

Cincinnati Children's Hospital Medical Center (Cincinnati Children's) will need to use and share your PHI as part of this study. This PHI will come from:

- Your medical records
- Your research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations
- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Who will share, receive and/or use your protected health information in this study?

- Staff at all the research study sites (including Cincinnati Children's)
- Personnel who provide services to you as part of this study
- Other individuals and organizations that need to use your PHI in connection with the research, including people at BioNTech/Pfizer and organizations that BioNTech/Pfizer may use to oversee or conduct the study.
- The Food and Drug Administration or similar agencies in other countries
- The members of the Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

As mentioned above, information about you that is sent outside the research site, including samples, will be assigned a numerical code. This code replaces your name when sending information and samples to the BioNTech/Pfizer or other recipients. BioNTech/Pfizer will use your coded information, including samples, to learn more about the study vaccine and viruses. BioNTech/Pfizer may also use your coded information and samples to design and conduct research in order to gain a further understanding of other diseases and to advance science, including development of other medicines for patients. BioNTech/Pfizer may share your coded information and samples with researchers and organizations collaborating with and providing services to BioNTech/Pfizer.

Can you change your mind?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI, you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?

Your permission for the study site to disclose your information does not expire unless you withdraw your permission.

Will your other medical care be impacted?

By signing this document you agree to participate in this research study and give permission to Cincinnati Children's to use and share your PHI for the purpose of this research study. If you refuse to sign this document, you will not be able to participate in the study. However, your rights concerning treatment not related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you should participate in this research, you will document your permission by signature below. You will receive a copy of this signed document for your records.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Date

_____ _____
Signature of Individual Obtaining Consent Date