	CT05-GSOP-RF05 7.0	PHASE 1/2/3 INFORMED CONSENT PEDIATRIC STUDY TEMPLATE	01-Jul-2019
Protocol Number: C4591007		ICD Version Date: 10 Sep 2021 Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing	
<input checked="" type="checkbox"/> Study <input type="checkbox"/> Country <input type="checkbox"/> Site	Language: English	Center ID: N/A	Country: N/A
ICD Derived From: N/A			

Dear Sir or Madam,

Thank you for taking the time to consider permitting your child to join this study. We understand that this may be a difficult decision. This consent document can help you make your decision by explaining **what you and your child can expect to happen during this study**, also known as a clinical trial or a research study.

Your child's participation in this study is **completely voluntary (your choice)**. You can take as long as you need to make your decision. You can also choose to allow your child to take part in the study now and have the option to change your mind later at any time. Please keep in mind that even if you allow your child to participate, it is possible that your child may not meet the study's entry requirements.

Depending on your child's age, mental status and local laws, the study team **may need to verify your child's agreement (called "assent") to participate in this study**.

We encourage you and your child to **have conversations with family, caregivers, doctors, and the study team** about taking part in this study and whether it is the right decision for your child. The study team will work with you and your child to answer all questions that you or your child may have about the study. The study team includes the study doctor, nurses, and other personnel who work with the study doctor.


If you choose to permit your child to participate in this study, **you will be asked to sign and date this consent document** prior to the study to let the study team know your decision.

You will receive a copy of this signed and dated consent document for your records. Please keep this consent document for your reference.

We appreciate that you are thinking of permitting your child to take part in this study.

Sincerely,

Study Doctor

	CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Ph2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL	Intro Page: 1 of 1
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








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FDA-CBER-2021-5683-1077848

CONSENT TO TAKE PART IN STUDY




Table of Contents

This Table of Contents describes the different sections of this consent document. Be sure to read through all sections of this consent document before making your decision about whether or not to participate in this study.


	Section	Page
	1. Key study information and contact information	3
	2. Brief summary of this study	4
	3. What is the purpose of this study?	6
	4. How long will my child participate in this study?	8
	5. How many children will take part in this study?	8
	6. What will happen during this study?	9
	7. Are there any special instructions to follow for this study?	17
	8. What are the possible risks and discomforts of this study?	17
	9. What are the possible benefits of this study?	21
	10. What other choices do I have if I do not want my child to join this study?	21
	11. What happens if my child is injured during this study?	21
	12. What if my child joins this study and then changes his/her mind?	21
	13. What will I have to pay for if my child takes part in this study?	22
	14. Will my child be paid for taking part in this study?	22
	15. What will happen to my child's personal information?	22

090177e1980ec546\Approved\Approved On: 13-Sep-2021 22:31 (GMT)

CONSENT TO TAKE PART IN STUDY

-  16. Where can I find additional information about this study or the study results? 22
-  17. Signatures 23
-  [Privacy Supplement](#)

090177e1980ec546\Approved\Approved On: 13-Sep-2021 22:31 (GMT)

	CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL	Page: 2 of 27 FDA-CBER-2021-5683-1077850
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CONSENT TO TAKE PART IN STUDY

1. Key Study Information and Contact Information

The study team will address any questions, concerns or complaints you or your child may have before, during and after your child completes the study. The study team includes the study doctor, nurses, and other personnel who work with the study doctor.

Phone numbers for the study team are listed below under “Study Site Contact Information.” **You will be given a card with important emergency contact information, including a 24-hour number.** Please show this card to any doctor, nurse or other health care provider if you seek emergency care for your child while they are taking part in this study. This card includes information about the study that will help them treat your child.

If you have any general questions about your child’s rights as a study participant, or would like to obtain information from, offer suggestions to, or speak with someone not directly involved in the study, you may contact [\[For the site-level ICD, include as appropriate: the Institutional Review Board or the Independent Ethics Committee, patient rights advocate, and/or bioethicist\]](#) listed below.

Name of Study: **A Phase 1, Open-Label Dose-Finding Study to Evaluate Safety, Tolerability, and Immunogenicity and A Phase 2/3 Placebo-Controlled, Observer-Blinded Safety, Tolerability, and Immunogenicity Study of a SARS-CoV-2 RNA Vaccine Candidate Against COVID-19 in Healthy Children and Young Adults**

Sponsor Consent Version Number (Study/Country/Site): **01 / 00 / 00**

[\[Institution\]](#) Study Number:

Sponsor Study Number: **C4591007**

Name of Company Sponsoring the Study: **BioNTech. Study conducted by Pfizer**

Name of Principal Investigator (Study Doctor):

Study Site Contact Information:

Contact Person:

Address:


Phone Number (Normal Business Hours):

Phone Number (Off-Hours or Emergency):

[\[Complete the following entries for the site-level ICD as appropriate.\]](#)

[\[Institutional Review Board or Independent Ethics Committee\]](#) Contact Information:

090177e1980ec546\Approved\Approved On: 13-Sep-2021 22:31 (GMT)

	CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL	Page: 3 of 27 FDA-CBER-2021-5683-1077851
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CONSENT TO TAKE PART IN STUDY

Contact Person:

Address:

Phone Number:

Patient Rights Advocate:

Contact Person:

Address:

Phone Number:

Bioethicist:

Contact Person:

Address:

Phone Number:


2. Brief Summary of this Study

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 and [study doctor/institution] will be paid to conduct this study.

This study is different from your child's regular medical care. The purpose of regular medical care is to improve or otherwise manage your child's health, but the purpose of research is to gather information to advance science and medicine and does not replace your child's regular medical care. If your child needs medical care during their time in the study, you should contact your regular provider and inform the study team, as described later in this document.

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). Since then, many companies around the world have quickly started to look for treatments and ways to prevent COVID-19. Children have been affected by primary COVID-19 disease and develop fever and dry cough over half the time. Symptoms also can include GI (Gastrointestinal) symptoms, including diarrhea and vomiting, and in some cases can be the only presenting features. In addition, children have also been affected by less common secondary inflammatory complications, including MIS-C (Multi-Inflammatory Syndrome-Children). MIS-C is a condition with fever and inflammation which can involve different organs of the body including heart, lungs, kidneys, brain, skin, eyes or gastrointestinal organs. It is currently not known what causes

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	<p>CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL</p>	<p>Page: 4 of 27 FDA-CBER-2021-5683-1077852</p>
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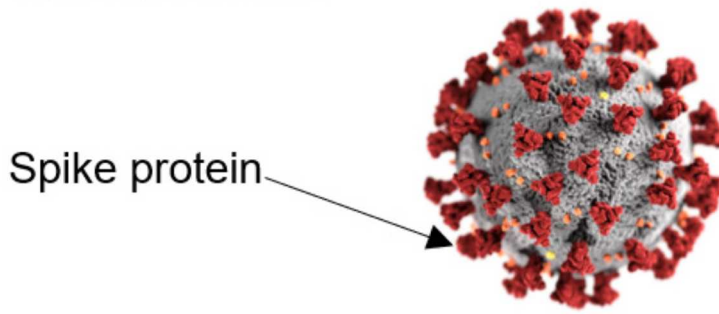
CONSENT TO TAKE PART IN STUDY

MIS-C, however, many children with MIS-C had COVID-19 or were exposed to COVID-19.

Vaccines help the body to produce antibodies to help fight off a disease. This research study involves an investigational (not approved by health authorities in children of the age being asked to volunteer for this study) vaccine to prevent COVID-19, that will be given to volunteers. The vaccine is given by injection in 2 doses.


These vaccines do not contain the whole virus, or the part of the virus that can make your child ill, instead the vaccines are made up of part of the virus's genetic code, surrounded by fatty particles called lipids. They use your child's cells' protein making machinery to produce some, or all, of the spike protein seen on the outside of the virus. This spike protein, made by your child's body, may help your child's body to produce antibodies to fight against COVID-19. We will check the level of antibodies your child makes by taking blood samples and testing them.

Coronavirus



Up until June 2021, the safety of BNT162b2 has been studied in clinical trials that have included about 28,500 people who have received at least one dose of the vaccine. In addition, since the vaccine has been approved for emergency use or received a conditional marketing in many countries, by the end of April 2021 about 400 million doses have been distributed. BNT162b2 was approved by the FDA on 23 August 2021 to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. Based on 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), being sick (vomiting), injection site redness, enlarged lymph glands, allergic reaction (symptoms may include rash, itching, hives, and swelling of the face or lips), decreased appetite, lethargy, sweating and night sweats, pain in arm, feeling weak or unwell, and severe allergic reaction (anaphylaxis).

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	<p>CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL</p>	<p>Page: 5 of 27 FDA-CBER-2021-5683-1077853</p>
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CONSENT TO TAKE PART IN STUDY

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. Symptoms include: Chest pain, shortness of breath, or feelings of having a fast-beating, fluttering or pounding heart. As a precaution, you should seek medical attention right away if your child has any of those symptoms after receiving the vaccine. The chance of having this occur is very low.

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

Allowing your child to take part in this study is voluntary (your and your child's choice). There is no penalty or change to you/your child or your child's regular medical care if you decide not to allow your child to participate. You can choose to allow your child 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 or your child are entitled. We encourage you and your child to have conversations with your family, caregivers, doctors, and study team about taking part in this study and whether it is right for your child. The study team will work with you and your child to answer any questions that you and your child may have about the study.

You will receive a copy of this signed and dated consent document for your records. Please keep this consent document for your reference.


You are being asked to allow your child to take part in a research study that will evaluate whether the investigational (study) vaccine to prevent COVID-19 is safe, tolerable and produces immune response to the virus causing COVID-19. This vaccine is given by an injection. You are being asked to allow your child to be in this research study because your child is healthy and meets the age requirement for this study.

Depending on your child's age, mental status and local laws, the study team **may need to verify your child's agreement (called "assent") to participate in this study.** Your child may give assent verbally, or they may be asked to print or sign their name on an assent document similar to this consent document. They may have an opportunity to meet privately with a member of the study team to ask confidential questions. Your child will also be able to decide not to take part for confidential reasons, which, if they request, would not be shared with you unless required by local law.

3. What is the purpose of this study?

The World Health Organization (WHO) has declared COVID-19 to be a pandemic (a disease that has spread all over the world and is affecting lots of people); finding a vaccine to prevent COVID-19 is an urgent need. To test this investigational vaccine as quickly as possible, this study will be conducted in several parts, which are described below.

090177e1980ec546\Approved\Approved On: 13-Sep-2021 22:31 (GMT)

	CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL	Page: 6 of 27 FDA-CBER-2021-5683-1077854
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CONSENT TO TAKE PART IN STUDY

Higher levels of a particular protein, called troponin I, found in the blood could be an early sign of myocarditis or pericarditis. Additional work is being undertaken to understand if a blood test for troponin I can be used as a sign of potential myocarditis or pericarditis. Blood samples will be drawn for possible troponin I testing in an additional group of participants, and if confirmed to be a reliable sign of potential myocarditis or pericarditis, testing for this heart enzyme will be done to help describe how often this may occur.

Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing. This is the part that you are being asked to allow your child to participate in. This part will be carried out in 2 age groups in order to collect blood samples for potential troponin I testing. The younger age group (5 to <12 years of age) will be placebo-controlled meaning the children will receive either active vaccine or placebo. The dose level for this age group is the same dose that is currently being tested in our ongoing Phase 2/3 study (10mcg). The older age group (12 to <16 years of age) will be open-label meaning everyone will receive active vaccine. The dose level for this age group is the same dose level currently EUA approved for this age group (30mcg). The children and adolescents in this part of the study will be:

- 12 to less than 16 years age, and
- 5 to less than 12 years of age.


If your child is 5 to <12 years of age, at approximately 6 months following the 2nd injection, you and your child will be informed by the study team whether your child was given the placebo injection or the active investigational COVID-19 vaccine at Visit 301 and Visit 302. If your child originally received placebo, your child will be offered the COVID-19 investigational vaccine.

If your child becomes eligible for a COVID-19 vaccine according to local or national recommendations before they are unblinded your study doctor will explain your options.

If your child turns 12 years of age, before 6 months following the 2nd injection, and was given placebo at Visit 301 and Visit 302, he or she has the following 2 options: receive a BNT162b2 10-µg dose within the study (following provision of informed consent) or receive a BNT162b2 30-µg dose outside of the study.

Please note, in May 2021 the U.S. Food and Drug Administration (FDA) that regulates vaccines issued an emergency use authorization (EUA) that allows individuals 12 through 15 years of age to receive BNT162b2 at 30-µg. An EUA is issued by the FDA to provide quick access to medical products, such as vaccines, that can be used when there are no other adequate, approved or available options during a public health emergency.

090177e1980ec546\Approved\Approved On: 13-Sep-2021 22:31 (GMT)

	<p>CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL</p>	<p>Page: 7 of 27 FDA-CBER-2021-5683-1077855</p>
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CONSENT TO TAKE PART IN STUDY

Other parts of the study:

Phase 1 Dose Finding. Please note that this part of the study has been completed. There were 3 age groups and the study looked at up to 3 dose levels in each age group. The children in this part of the study were:

- 5 to less than 12 years of age,
- 2 to less than 5 years of age, and
- 6 months to less than 2 years of age

Phase 1 Lower Dose Evaluation. This part will be carried out in 3 age groups and will look at up to 2 dose levels. The age groups in this part of the study will be:

- 16 to less than 30 years of age,
- 12 to less than 16 years of age, and
- 5 to less than 12 years of age.

Phase 2/3 Selected Dose. In this part we will use a dose level selected from the Phase 1 Dose Finding part of the study. This step of the study will collect information from a larger number of children about the safety of the vaccine and the amount of antibodies produced by the vaccine. In this Phase, everyone will receive either active vaccine or placebo. The children in this part of the study will be:

- 5 to less than 12 years of age,
- 2 to less than 5 years of age, and
- 6 months to less than 2 years of age.

Phase 2/3 Lower Dose Evaluation. In this step of the study we will use a dose level selected from the Phase 1 part of the study. This step of the study will collect information from a larger number of children and young adults about the safety of the vaccine and the amount of antibodies produced by the vaccine. In this part of the study, everyone will receive active vaccine. The age groups in this part of the study will be:

- 16 to less than 30 years of age,
- 12 to less than 16 years of age, and
- 5 to less than 12 years of age.


4. How long will my child participate in this study?

Your child will be in this study for about 6 months.

5. How many children will take part in this study?

The total number of children taking part in the whole study will depend on the results seen during the study. It is expected that approximately 1250 children will take part in

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	<p>CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL</p>	<p>Page: 8 of 27 FDA-CBER-2021-5683-1077856</p>
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CONSENT TO TAKE PART IN STUDY

the **Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing** part of the study.

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.

6. What will happen during this study?

Before any study procedures begin, or before you begin preparing your child for the study, you will be asked to read and sign this consent document. Depending on local law and your child's age, your child's permission may be required for the study team to share some of their test results with you.

After signing and dating this consent document, the study doctor will check if your child meets all the requirements to take part in this study. If your child does not meet the requirements, they will not be able to take part in the study and the study doctor will explain why this is the case. Similarly, if your child qualifies to take part in this study, the study doctor will explain this as well.

Study Vaccines


If your child is 5 to <12 years of age, once the study doctor has confirmed that they meet the study requirements, your child will be randomly assigned (like flipping a coin) to receive the study vaccine or placebo. For every 2 volunteers who receive the investigational COVID-19 vaccine, 1 volunteer will receive placebo. No one (including you, your child, your child's personal doctor or the study team) can choose this assignment.

This part of the study is a 'placebo-controlled observer-blinded phase' which means that you, your child and the study doctor **will not know** whether your child will be receiving the investigational COVID-19 vaccine or placebo. The person who gives your child the injection will know because the investigational COVID-19 vaccine and placebo do not look the same. The syringe will be covered with a label so the contents are not visible and the person that gives your child the injection will not be able to talk about it. In case of urgent need, the study doctor can learn quickly whether your child received study vaccine or placebo.

If your child is 12 to <16 years of age, once the study doctor has confirmed that they meet the study requirements, your child will receive active study vaccine.

The vaccine will be given to your child through an injection into the muscle in their upper arm. Each participant will receive two injections, approximately three weeks apart. On the days your child receives the injection, you will be asked to wait with your child at the study site for at least 30 minutes for observation after they receive injection.

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	CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL	Page: 9 of 27 FDA-CBER-2021-5683-1077857
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CONSENT TO TAKE PART IN STUDY

Study Vaccines – after participating in the study for approximately 6 months after receiving second injection

If your child is 5 to <12 years of age, when you and your child come for your child's visit at approximately 6-months after their second injection, you and your child will be told if your child was given the investigational COVID-19 vaccine (BNT162b2) or placebo injection.


If your child was given the investigational COVID-19 vaccine as their injection 1 and 2, your child will not need any further injections in the study.

If your child was given the placebo injection as their injection 1 and 2, they will be offered two doses of active vaccine. The first dose of investigational COVID-19 vaccine (active) will be given as a third injection. Approximately 3 weeks later, your child will be given a 4th injection which is the second dose of the investigational COVID-19 vaccine. For this part, the study will be 'unblinded', meaning that you, your child and your doctor **will know** that your child is getting the investigational COVID-19 vaccine.

Overview of Study Procedures and Assessments

The table below lists the tests and procedures or assessments that your child will have done at each of their visits during this phase of the study. You will have the following tests, procedures or assessments during this study. In addition to the visits listed, your child's study doctor may ask you to bring your child in for extra visit(s) if necessary, to protect your child's well-being. It is important that your child and you attend each visit on the day that your research study team arranges for your child.

090177e1980ec546\Approved\Approved On: 13-Sep-2021 22:31 (GMT)

	CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL	Page: 10 of 27 FDA-CBER-2021-5683-1077858
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CONSENT TO TAKE PART IN STUDY

For the participants taking part in Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing, the study doctor or nurse will perform the following assessment and procedures:

Summary of Planned Study Visits and Procedures for ALL Participants up to 6-months after Vaccine 2:

Visit Number	301	302	303	304	305
Types of Visit	Clinic	Clinic	Clinic	Telephone	Telephone
Visit Description and Visit Timing	Study Vaccine 1	Study Vaccine 2	4-Day Follow-up Visit	1-Month Follow-up Visit	6-Month Follow-up Visit
Review and sign informed consent document	X				
Ask about medical history as well as date of birth, sex, race and ethnicity	X				
Measure pulse rate, respiratory rate, blood pressure, and body temperature	X	X			
Perform clinical assessment	X	X			
If your child is HIV positive, ask for their latest CD4 counts and HIV viral load	X			X	X
If your child is a female and if able to have children, she will be asked to provide a urine sample for a pregnancy test	X	X			
If needed, the study team will discuss and confirm the use of appropriate birth control with your child	X	X	X	X	
Ask about medications your child is currently taking		X	X	X	X



CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019)
 TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site)
 Sponsor Consent Version Number (Study/Country/Site) : [1/0/0]
 Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021

Protocol No. C4591007/PFIZER CONFIDENTIAL

Page:
11 of 27

FDA-CBER-2021-5683-1077859

CONSENT TO TAKE PART IN STUDY

Visit Number	301	302	303	304	305
Types of Visit	Clinic	Clinic	Clinic	Telephone	Telephone
Visit Description and Visit Timing	Study Vaccine 1	Study Vaccine 2	4-Day Follow-up Visit	1-Month Follow-up Visit	6-Month Follow-up Visit
Ask about any other vaccines your child has been given	X	X	X	X	X
Check your child meets all the study requirements	X	X			
Take a nasal swab for the detection of virus causing COVID-19	X	X			
Collect blood sample (approximately 5 mL at each time)	X		X		
Give vaccine injection in your child's arm and observe for 30-min following injection	X	X			
You will be shown/reminded how to use the e-diary (or the study team will assist you to download an app), and at Visit 301 you will be given a thermometer and a caliper (measuring device)	X	X			
You will be asked to complete a vaccination e-diary for 7 days to record potential side effects following each vaccination	X	X			
Ask how your child is feeling or if your child is having any potential side effects	X	X	X	X	X
Inform you and your child about which vaccine your child was given at Visit 301 and Visit 302					X



CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019)
 TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site)
 Sponsor Consent Version Number (Study/Country/Site) : [1/0/0]
 Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021
 Protocol No. C4591007/PFIZER CONFIDENTIAL

Page:
12 of 27

CONSENT TO TAKE PART IN STUDY

Summary of Planned study Visits and Procedures for Participants 5 to <12 years who originally received Placebo at Visit 301 and Visit 302:

Visit Number	A1	B1	C1	D1
Types of Visit	Clinic	Clinic	Telephone	Telephone
Visit Description and Visit Timing	Study Vaccine 3	Study Vaccine 4	1-Month Follow-up Visit after vaccine 4	6-Month Follow-up Visit after vaccine 4
Inform you and your child that your child originally received placebo	X			
Measure pulse rate, respiratory rate, blood pressure, and body temperature	X	X		
Perform clinical assessment	X	X		
If your child is HIV positive, ask for their latest CD4 counts and HIV viral load	X		X	X
If your child is a female and if able to have children, she will be asked to provide a urine sample for a pregnancy test	X	X		
If needed, the study team will discuss and confirm the use of appropriate birth control with your child	X	X	X	
Ask about medications your child is currently taking	X	X	X	X
Take a nasal swab for the detection of virus causing COVID-19	X	X		
Collect blood sample (approximately 5 mL) <i>Blood draw is only for participants who become eligible for receipt of BNT162b2 or another COVID-19 vaccine according to local or national recommendations prior to Visit 303.</i>	X			



CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019)
 TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site)
 Sponsor Consent Version Number (Study/Country/Site) : [1/0/0]
 Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021
 Protocol No. C4591007/PFIZER CONFIDENTIAL

Page:
13 of 27

CONSENT TO TAKE PART IN STUDY

Visit Number	A1	B1	C1	D1
Types of Visit	Clinic	Clinic	Telephone	Telephone
Visit Description and Visit Timing	Study Vaccine 3	Study Vaccine 4	1-Month Follow-up Visit after vaccine 4	6-Month Follow-up Visit after vaccine 4
Give investigational COVID-19 vaccine injection in your child's arm and observe for 30-min following injection	X	X		
Ask how your child is feeling or if your child is having any potential side effects	X	X	X	X



CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019)
 TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site)
 Sponsor Consent Version Number (Study/Country/Site) : [1/0/0]
 Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021
 Protocol No. C4591007/PFIZER CONFIDENTIAL

Page:
14 of 27

CONSENT TO TAKE PART IN STUDY

6. Description of Study Procedures and Assessments

Biological Samples

The following blood and nasal biological samples will be taken in this study. Your child must provide these samples in order to take part in this study. The samples may be stored in a facility located in a different country from your study site.

Your child's blood and nasal 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 child's 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. No testing of your child's DNA will be performed. You and your child will not be told of additional tests, nor will you or your child receive results of any of these tests except for nasal swab test results which will be communicated to your child's study team doctor as described later in this section.

Blood Samples for antibody testing:

All participants will have a blood sample taken at the following 2 planned visits: Visit 301 and Visit 303.

Each blood sample will be approximately 5 mL and will be collected using a needle.


Your child's blood samples may be used to test for troponin I levels.

Nasal Swabs for detection of coronavirus causing COVID-19:

Your child will have nasal swab collected from his/her nose 2 times during the planned study visits. A swab (which looks like a Q-tip) will be inserted into your child's nose to collect any fluid or mucus. These samples will be tested to detect the presence of coronavirus causing COVID-19. Results of nasal swabs at Visit 301 and Visit 302 (and Visit A1 and Visit B1 if your child originally received placebo and goes on to receive investigational COVID-19 vaccine) will be provided to your study doctor, however, this will take some time so you should not rely on this information for your child's medical treatment.

Urine Samples:

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	<p>CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL</p>	<p>Page: 15 of 27 FDA-CBER-2021-5683-1077863</p>
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CONSENT TO TAKE PART IN STUDY

If your child is female who is able to have children in the opinion of study doctor, your child will need to provide a urine sample for pregnancy testing to check she is not pregnant before she is given the study vaccine injection. If your child has a positive urine pregnancy test result, the study doctor will share the information with you and your child will not be able to participate in the study.

E-Diary:

At Visit 301, the study team will explain what you need to do and show you how to fill in an electronic diary (or e-diary). As a parent(s)/legal guardian(s), as appropriate, you will be required to complete the e-diary for your child. We will either give you a device (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 also be given a thermometer and a measuring device (caliper).

The e-diary will prompt you to answer questions about how your child is feeling after receiving the injection. At the Visit 301 and Visit 302, you will be instructed by the study team to complete the e-diary every evening for 7 days after each injection is given to your child. Day 1 of the e-diary completion will begin on the evening your child receives the injection and the following next 6 days (7 days in total). You will use the thermometer to measure your child's temperature. This temperature measurement will be oral (under his/her tongue). You will then enter the temperature reading into the e-diary. The measuring device will be used to measure the size of any redness or swelling on your child's arm where the injection was given. You will need to enter these measurements in the e-diary. It is important that all of the requested information is entered in the e-diary.


The e-diary will also ask other questions about potential side effects your child may have after the injection. If your child has any severe symptoms after vaccination, you should contact your child's study doctor and the study doctor or nurse may schedule an extra unplanned visit to evaluate your child.

What happens if my child is participating and has a positive nose swab test result after Visit 301 or Visit A1 (if your child originally received placebo and goes on to receive investigational COVID-19 vaccine at Visit A and B) but before the next planned injection visit?

If your child has any potential COVID-19/MIS-C symptoms with a positive nose swab test result after the Visit 301 or Visit A1 (if your child received placebo), your child's study team may need to delay the planned injection until your child becomes well.

If your child has a positive nose swab test result after Visit 301, without the presence of any potential COVID-19/MIS-C related symptoms, your child will be given the injection as planned in the study.

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	<p>CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL</p>	<p>Page: 16 of 27 FDA-CBER-2021-5683-1077864</p>
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CONSENT TO TAKE PART IN STUDY

Leaving the Study Early

You or your child, may withdraw 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 or your child decide to leave the study, you/your child will be asked why you would like to withdraw.

After the study

The study vaccine is available only during this study and not after the study is over.

7. Are there any special instructions to follow for this study?


It is important that you and your child follow all the instructions given to you by the study nurse or study doctor and tell them if:

- You or your child do not understand anything about the study
- You or your child will not be able to comply with the study requirements
- There are changes in your child's health
- Your e-diary device or APP is not working properly
- Your child takes any new medications or receives any other vaccines
- You or your child are going away for a long period
- 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 is currently involved in any other study
- Notify the study team if you/your child moves and provide your/your child's new contact information.

8. What are the possible risks and discomforts of this study?

Any research has some risks, which may include negative effects that could make your child 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.

If your child takes part in this study, the most likely risks or discomforts are discussed below.

	<p>CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL</p>	<p>Page: 17 of 27 FDA-CBER-2021-5683-1077865</p>
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CONSENT TO TAKE PART IN STUDY

It is important that you/your child report to the study team all symptoms and side effects as soon as they occur. Phone numbers for the study team are listed in [Section 1] of this consent document.

Up until June 2021, the safety of BNT162b2 has been studied in clinical trials that have included about 28,500 people who have received at least one dose of the vaccine. In addition, since the vaccine has been approved for emergency use or received a conditional marketing authorization in many countries, by the end of April 2021 about 400 million doses have been distributed.

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

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, hives), decreased appetite, lethargy, sweating and night sweats, pain in arm, and feeling weak or unwell.

Rare (between 1 in 1,000 and 1 in 10,000 people): swelling of the face or lips.


Frequency that cannot be estimated from available data: severe allergic reaction (anaphylaxis).

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 as your child may need to come in for an assessment.

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	CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL	Page: 18 of 27 FDA-CBER-2021-5683-1077866
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CONSENT TO TAKE PART IN STUDY

Whilst 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 study doctor.

As in all research studies, the COVID-19 vaccine 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 my 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. It remains important for you/your child to contact your child's study doctor if your child develops symptoms that might be caused by COVID-19 (for example, fever, cough, shortness of breath).


Placebo Risks

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

Risks from Study Procedures

Risks and possible discomforts your child might have from the study procedures include:

- **Blood Samples:** The risks and possible discomforts involved in taking blood include pain from inserting the needle, or less often, swelling, bruising, or infection around the vein where the blood is collected. Your child may feel dizzy or may faint. If your child has a previous history of feeling dizzy or fainting during blood sample collection you should talk to the study doctor.

	CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL	Page: 19 of 27 FDA-CBER-2021-5683-1077867
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CONSENT TO TAKE PART IN STUDY

- Nasal Swabs: The risks and possible discomfort involved in taking nasal swabs may include pain or general discomfort. Sometimes it may cause the nose to bleed.

Pregnancy-Related Risks; Use of Birth Control

If your child is currently pregnant, plans to become pregnant, or is breastfeeding a child, she should not join this study. If your child is a male, he should not father a baby while taking part in this study.

If your child is able to have children and is sexually active, they must use birth control consistently and correctly for the duration of the study including and for at least 28 days after they receive their last planned injection. This applies to male participants as well as female participants who take part in the research study. The study doctor will discuss with your child the methods of birth control that they should use while in this research study, if appropriate. The study doctor will help your child select the method that is appropriate for them. The study doctor will also check that your child understands how to use the birth control method and may review this with them at visits specified in the Section 6 in the tables describing study visits, if appropriate.

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


If abstinence (not having sexual intercourse at all) is your child's current lifestyle, and both you/your child and the study doctor agree that it is your child's selected method of contraception, your child must continue not to have sexual intercourse for at least 28 days after the last planned injection.

As permitted by local law, the study doctor may: (a) provide confidential contraceptive counseling to your child (not discussed with you) and (b) help your child to assess additional reproductive services, if needed. The study doctor will instruct your child about how to use their selected birth control method correctly and consistently and may review this with your child at visits specified in the Section 6 in the tables describing study visits.

Pregnancy Follow-up

If your child or their partner become pregnant during the study, up until 28 days after your child's last study injection, please tell the 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. Please also tell the doctor who will be taking care of your child/their partner during the pregnancy that your child took part in this study. The study doctor will ask if your child/their partner or their pregnancy doctor is willing to provide updates on the progress of the pregnancy and its

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	CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL	Page: 20 of 27 FDA-CBER-2021-5683-1077868
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CONSENT TO TAKE PART IN STUDY

outcome. If your child/their partner agree, this information will be provided to the BioNTech/Pfizer for safety follow-up.

9. What are possible benefits of this study?

Vaccination with BNT162b2 has been shown to be effective in preventing COVID-19 in the people already studied who are 12 years and older. Continue to follow local recommendations about how to avoid COVID-19 (for example, social distancing and mask use). In addition, information learned from the research study may help other people in the future.

10. What other choices do I have if I do not want my child to join this study?

This study is for research purposes only. The only alternative is to not take part in this study.

11. What happens if my child is injured during this study?

For mandatory research injury language, [<click here>](#) (retain this link in the study-level ICD). The country-specific research injury language must be included verbatim in the country-level ICD.

12. What if my child joins this study and then changes his/her mind?


You are free to withdraw your child from this research study at any time. Tell the study doctor if you are thinking about this so that your child may end the research study in the safest way. The research study team will also tell you if new information is learned that could change your/your child's mind about your child's continuation in this research study. Your decision will not affect the medical care your child receives, and your child will not lose any benefits to which he/she would otherwise be entitled.

While your child is participating, the study team will tell you in a timely manner if new information is learned during the course of the study that could change your/your child's mind about continuing. If you decide to withdraw your child from receiving vaccine or if your child decides to withdraw from receiving vaccine, your child may be asked to continue to participate in the study procedures even though they would no longer take the study vaccine.

If your child continues with the follow-up part of the study, information about your child's health will continue to be collected as described in [\[Section 6\]](#).

If you decide to stop your child participating in this study, you must notify the study doctor. The study team will explain what other procedures or discussions should occur.

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	CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL	Page: 21 of 27 FDA-CBER-2021-5683-1077869
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CONSENT TO TAKE PART IN STUDY

Sometimes the study doctor or BioNTech/Pfizer may decide to take your child out of the study (even if you do not agree) if:

- You/your child are unable or unwilling to follow the instructions of the study team;
- The study doctor decides that the study is not in your child's best interest or that they are no longer eligible to participate; or
- The study is stopped by the BioNTech/Pfizer, the Institutional Review Board (IRB) or Independent Ethics Committee (IEC) (a group of people who review the study to protect your/your child's rights), or by a government or regulatory agency.

The study team will give you a Privacy Supplement, which is considered part of this consent document. It describes what happens to your/your child's personal information (including your child's biological samples) and how it may be used if you withdraw your child from the study or if your child withdraws from the study.

13. What will I have to pay for if my child takes part in this study?

You will not need to pay for the study vaccine, study-related procedures, or study visits.

14. Will my child be paid for taking part in this study?

You will not receive any payment for your child taking part in this study. However, for each visit you/your child completes, you/your child will be reimbursed by the study site to cover reasonable expenses (for example, parking, meals, travel) that you have as a result of your child taking part in this study. You/your child will be reimbursed by [\[enter, as applicable, method of reimbursement; amounts; and reimbursement schedule; note whether receipts are required\].](#)

BioNTech/Pfizer may use information resulting from the study to develop products or processes from which it may make a profit. There are no plans to pay you/your child or provide you with any products developed from this study. BioNTech/Pfizer will own all products or processes that are developed using information from the study.


15. What will happen to my child's personal information?

[<Click here>](#) for language to be inserted into this section. This text must be inserted [verbatim](#). Any requested changes must be approved by Clinical Development Legal. Note that the Privacy Supplement follows this consent document, after the signature section.

16. Where can I find additional information about this study or the study results?

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify your

090177e1980ec546\Approved\Approved On: 13-Sep-2021 22:31 (GMT)

	CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL	Page: 22 of 27 FDA-CBER-2021-5683-1077870
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CONSENT TO TAKE PART IN STUDY

child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The study results, when available, may also be found on www.pfizer.com and <https://www.clinicaltrialsregister.eu/>.

In addition, a plain summary of the study results will be made available in the EU database at [\[insert link to the database\]](#). This information will be provided no matter what the study's outcome. To the extent possible, you will be able to access these summaries in the EU database soon after they become available using the following EU trial number for the study: [\[insert trial number\]](#).

These websites are in English only. If you need assistance understanding these Web sites, please ask a member of the study team.

BioNTech/Pfizer will provide the study doctor with information about the study results when all participants have completed the study. At that time, certain of your child's individual study results may be given to you or your child's doctor (if different from the study doctor) in accordance with applicable law, but will not be given to your/your child's family, your employer or any insurance company.

If any exploratory research is done, it may not be possible to link any results from that exploratory research to specific individual, including your child. BioNTech/Pfizer does not plan to return information from any exploratory research to you/your child, the study doctor, or your child's doctor (if different from the study doctor).

17. Signatures

The column for subject initials in the table below may be removed if not required by the IRB/IEC, regulatory agencies, and/or other similar reviewers.

Agreement to Participate and to Process Data	Initials
1. I confirm I have read (or, if I cannot read, a study team member has read to me) and understand this consent document for the study described above and have had the opportunity to ask questions. I have had enough time to review this consent document. I also have had an opportunity to ask about the details of the study and to decide whether or not I want my child to participate.	
2. I have read and understand the Privacy Supplement. I understand that taking part in the study will require the processing (including collection, use, transfer, storage, analysis and reporting) of my child's personal information, as explained in the Privacy Supplement. I understand and agree	

CONSENT TO TAKE PART IN STUDY

<p>to the processing of my child’s personal information within and outside my country of residence for health care, medical research and/or regulatory purposes.</p>	
<p>3. I understand that allowing my child to take part is voluntary and that I am free to stop my child taking part in this study or to withdraw my consent to the processing of my child’s personal information at any time. I do not need to give any reason and my child’s regular medical care and legal rights will not be affected. However, even if I withdraw my consent to processing, my child’s personal information held at that time may be kept to comply with laws and regulations and to maintain the integrity of the study. I also understand that my child’s biological samples may not be able to be destroyed because they may no longer be traceable to my child, may have already been used, or may have been given to a third party.</p>	
<p>4. I agree to the study team accessing my child’s medical history, including information from medical records and test results and any medical treatment my child receives during the course of the study, and if necessary, contacting my child’s doctor or any other health care providers treating my child for access to such information.</p>	
<p>5. I understand that BioNTech/Pfizer and/or others working with or on behalf of the BioNTech/Pfizer, Institutional Review Boards (IRBs) or Independent Ethics Committees (IECs), and regulatory agencies may need access to personal information about my child generated at the study site or collected by the study team for the study and any other research. I agree that they may have access to my child’s personal information.</p>	
<p>6. I do not give up any of my child’s legal rights by signing and dating this consent document. I have been told that I will receive a copy of this signed and dated document.</p>	
<p>7. I agree for my child to take part in the study described in this document.</p>	

090177e1980ec546\Approved\Approved On: 13-Sep-2021 22:31 (GMT)

CONSENT TO TAKE PART IN STUDY

In the section below, the term “legally acceptable representative” should be replaced with the term required per local regulation (country-level).

Signature Lines to be Included:

Printed name of participant

As the consenting adult providing permission for this child to participate in the study, I acknowledge that (Please check one of the following):

- I am the biological or adoptive parent of the child.
- I am the legal guardian or legally acceptable representative of the child.

[If neither option below is checked, then the consent of the second parent/guardian/legally acceptable representative must be obtained. If there are two parents/guardians/legally acceptable representatives available to give permission, and they disagree about allowing the child to participate in the study, the child should not be enrolled unless that disagreement can be resolved.] Page 25 of 28

I also acknowledge that (Please check one of the following):


- I have sole legal responsibility for the care and custody of the child.
- The other adult(s) with whom I share legal responsibility for the care and custody of the child (for example, biological parent, adoptive parent, or legal guardian or representative) is (1) aware of and agrees with my granting permission for this child to participate in the study OR (2) deceased, unknown, incompetent, or not reasonably available (someone is “not reasonably available” when he/she cannot be reached by phone/mail/email because, for example, he/she is on active military duty or is incarcerated).

Printed name of parent/guardian/legally acceptable representative

Signature of parent/guardian/legally acceptable representative

Date of signature[§]

[Include the statements and signature lines below for a second parent/guardian/legally acceptable representative if (1) required by the IRB/IEC; (2) required by local law (e.g., parents are divorced and have shared custody of the child); or (3) the second parent/guardian/legally acceptable representative is (or would like to be) involved in the

	CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL	Page: 25 of 27 FDA-CBER-2021-5683-1077873
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CONSENT TO TAKE PART IN STUDY

consent process and there is reason to believe that he/she may disagree with the decision of the first parent/guardian/legally acceptable representative.

Consent of Second Parent/Guardian/Legally Acceptable Representative:

As the consenting adult providing permission for this child to participate in the study, I acknowledge that (Please check one of the following):

- I am the biological or adoptive parent of the child.
- I am the legal guardian or legally acceptable representative of the child.

Printed name of parent/guardian/legally acceptable representative

Signature of parent/guardian/legally acceptable representative

Date of signature[§]

[If local IRB/IEC permits assent of older children to be obtained by co-signature, include the following:

Participant's Assent:

Signature of participant

Date of signature[§]

Person Obtaining Consent:


Printed name of person conducting the consent discussion

Signature of person conducting the consent discussion[†]

Date of signature

[§] Parent/guardian/legally acceptable representative must personally date their respective signatures.


[†] The investigator, or an appropriately qualified and trained person designated by the investigator to conduct the informed consent process, must sign and date the consent document during the same discussion when the participant's parent/guardian/legally acceptable representative signs the consent document.

	CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL	Page: 26 of 27 FDA-CBER-2021-5683-1077874
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PRIVACY SUPPLEMENT

For mandatory country-specific data privacy language to be inserted in this Privacy Supplement, [<click here>](#) (retain this link in the study-level ICD). The country-specific data privacy language must be included verbatim in the country-level ICD. Any requested changes must be approved by Clinical Development Legal.

090177e1980ec546\Approved\Approved On: 13-Sep-2021 22:31 (GMT)

	<p>CT05-GSOP-RF05 7.0 Phase 1/2/3/4 Informed Consent Pediatric Study Template (01-Jul-2019) TMF Doc ID: 173.13 (Study); 173.07 (Country/Central); 173.23 (Site) Sponsor Consent Version Number (Study/Country/Site) : [1/0/0] Phase 2/3 Obtaining Serum Samples for Potential Troponin I Testing (all age groups) 13 Sep 2021 Protocol No. C4591007/PFIZER CONFIDENTIAL FDA-CBER-2021-5683-1077875</p>	<p>Page: 27 of 27</p>
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