Protocol Number: C4591020		**ICD Version Date: 02 Feb 2021**	
☑ **Study** ☑ **Country** ☐ **Site**	**Language: English**	**Center ID:** Not Applicable	**Country:** US
ICD Derived From: C4591020, ICD Version Date: 20-Jan-2021			

CONSENT DOCUMENT COVER LETTER

This is a welcome letter to the study participant that explains the purpose of the consent document, emphasizes that the study is voluntary, and generally introduces the participant to the study. This letter should not be edited to include technical study information contained in the main consent document or in the Additional Consent Request. This letter may be deleted if required by an IRB/IEC, regulatory agency, or other similar reviewer; the ICD required elements listed below are also included in Section 2 of the ICD.

ICD required elements to be covered in this section: (1) participation is voluntary; (2) there is time to decide and ask questions; and (3) a copy of the signed ICD is given to the participant prior to participation.

Dear Sir or Madam,

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

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

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

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

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

We appreciate that you are thinking of taking part in this study.

Sincerely,

_____
Study Doctor

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.

1. Key Study Information and Contact Information

The study team will address any questions, concerns or complaints you may have before, during and after you complete the study. The study team includes the study doctor, nurses, and others who work with the study doctor.

Phone numbers for the study team are listed below under "Study Site Contact Information." **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.

If you have any general questions about your 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 3, RANDOMIZED, OBSERVER-BLIND STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND IMMUNOGENICITY OF A LYOPHILIZED FORMULATION OF THE VACCINE CANDIDATE BNT162b2 AGAINST COVID-19 IN HEALTHY ADULTS 18 THROUGH 55 YEARS OF AGE**

Sponsor Consent Version Number (Study/Country/Site): / /

[Institution] Study Number:

Sponsor Study Number: **C4591020**

Name of Company Sponsoring the Study: **BioNTech. Pfizer is conducting the study for BioNTech**

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:

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

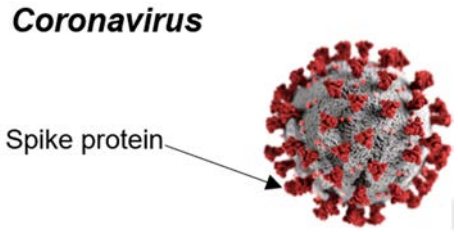
This is a research study involving both Pfizer and BioNTech. Pfizer and BioNTech are separate companies who are cooperating to perform this study. Pfizer is responsible for conducting this study. BioNTech is the regulatory sponsor of this study. Funding for this study is provided by BioNTech and Pfizer and [the study doctor/institution] 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). Since then, many companies around the World have quickly started to look for treatments and ways to prevent COVID-19. There are no currently licensed (approved for sale) vaccines for COVID-19. The investigational vaccine in this study received the first approval for emergency use in the United Kingdom on December 2nd 2020 and in the U.S. on December 12th 2020. Other countries have also authorized temporary or emergency use. Your study doctor can provide you with more information about the availability of this vaccine and other COVID-19 investigational vaccines that are approved for emergency use.

Vaccines help your body to produce antibodies to help you to fight off a disease. This research study involves an investigational vaccine to prevent COVID-19, that will be given to healthy volunteers. The vaccine is given by injection. The purpose of this study is to learn about the safety, and amount of antibodies made after injection (immune responses), of up to 3 separate versions of this vaccine. The three versions are; the frozen liquid multi dose vial that has been granted emergency use in the U.S. and other countries, a lyophilized (freeze-dried) single dose vial, and a lyophilized (freeze dried)

multi-dose vial that may contain a preservative. The lyophilized version will allow for storage at standard refrigerator temperatures. When the study begins (first participant enrolled), participants will receive either the lyophilized single-dose version or the frozen liquid multi dose vial that has been granted emergency use in the U.S. and other countries. The lyophilized multi dose vial version (which may contain a preservative) will not be available when the study begins and may not be studied. Each participant will receive one of the vaccine versions. There is no placebo in this study (a placebo does not contain any active ingredients).

This investigational vaccine, called BNT162b2, is a RNA vaccine and does not contain the whole virus, or the parts of the virus that can make you ill; instead, the vaccine is made up of part of the virus's genetic code (RNA), surrounded by fatty particles called lipids. It uses your own cells' protein-making machinery to produce the spike protein seen on the outside of the virus. This spike protein, made by your own body, may help your body to produce antibodies to fight against COVID-19. We will check how many antibodies you make by taking blood samples and testing them.



Up until the end of 2020, the safety of BNT162b2 has been studied in clinical trials that have included 21,744 people 16 yrs of age and older who have received at least one dose of the vaccine. In addition, since the vaccine has been approved for emergency use in many countries, about 26 million doses have been distributed. 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, joint aches, muscle aches, feeling sick (nausea), injection site redness, enlarged lymph glands, allergic reaction (symptoms may include rash, itching, hives, and swelling of the face or lips), pain in arm, feeling weak or unwell, and severe allergic reaction (anaphylaxis)..

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

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

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. We encourage you to have conversations with your family, caregivers, doctors, and study team about taking part in this study and whether it is right for you. The study team will work with you to answer any questions that you may have about the study.

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

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.

The purpose of this study is to evaluate a lyophilized and frozen liquid version of this investigational vaccine (BNT162b2). We would like to collect more information about the safety of the vaccine and the amount of antibodies that it produces, and see whether all the different versions produce a similar response. The vaccine will only be given in this study to adults 18 through 55 years of age who have not previously received any vaccine against COVID-19.

The study doctor will determine whether you are eligible for the study. This study will require you to visit the study doctor to undergo study procedures and to provide information about your health.

4. How long will I participate in this study?

You will be in this study for about 2 months. You will need to visit the study site at 3 planned times during the study. The study doctor may ask you to visit the site (or have a phone or video call) in between planned visits, if needed.

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

There will be about 550 (or 1100 if the lyophilized multidose vial is studied) healthy people taking part in this study. This study is being done at about 20 different study sites across the United States.

6. What will happen during this study?

Before any study procedures begin, or before you begin preparing for the study, you will be asked to read and sign this consent document.

After signing this consent document, the study doctor will check if you meet all of the requirements to take part in this study. If you do not meet the requirements, you will not be able to take part in the study and the study doctor will explain why this is the case.

Study Vaccines

Once the study doctor has confirmed you meet the study requirements, you will be randomly assigned (like flipping a coin) to receive 1 of the 2 study vaccine versions, either the freeze-dried refrigerated type or the frozen type. Half of the people in the study will receive the freeze-dried refrigerated type and the other half will receive the frozen type. As there is no placebo in this study, all participants will receive the study vaccine.

This is an 'observer-blind study', which means that you and the study doctor will not know which version of the study vaccine you are receiving, but the person who gives you the vaccine will know. However, the syringe will be covered with a label so the contents are not visible and the person who gives you the vaccine will not be able to talk about it with you. In case of urgent need, the study doctor can learn quickly which version of study vaccine you have received.

The study vaccine will be given to you through an injection into the muscle in your upper arm. Everyone will receive 2 injections, approximately 3 weeks apart. On the days you receive the study vaccine, you will be asked to wait at the study site for at least 30 minutes for observation after receiving the study vaccine.

Overview of Study Procedures and Assessments

The table below lists the tests and procedures or assessments that you will have done in this research study. In addition to the visits listed, your study doctor may ask you to come in for extra visit(s) if necessary, to protect your well-being.

The study doctor or nurse will:

Visit Number	1	2	3
		(19-23 days after Visit 1)	(28 to 35 days after Visit 2)
Visit Description	**Study Vaccine 1**	**Study Vaccine 2**	**1-Month Follow-up Visit**
Ask about Medical history as well as date of birth, sex, race and ethnicity	X		
Perform clinical assessment or physical exam	X		
Measure height and weight	X		
Measure body temperature	X	X	
Urine pregnancy test (if appropriate)	X	X	
Check contraceptives (if appropriate)	X	X	X
Ask about other vaccinations you have had	X	X	X
Ask about medicines you are currently taking		X	X
Check you meet all the study requirements	X	X	
Collect blood sample to test antibody levels	~20 mL		~20 mL
Take a nasal swab for COVID-19 virus detection	X		X
Give the study injection, followed by a 30-minute observation period	X	X	
Give you an e-diary or help you download one	X	X	
Explain the vaccination e-diary completion for participants to self-report potential side effects for 7 days following each vaccination	X →	X →	
Ask how you are feeling generally	X	X	X
Collect e-diary or help you to delete the application			X

Blood samples for antibody testing

You will have blood taken 2 times during the planned visits of the study at Visit 1 and at Visit 3. This will be used to test if you already had antibodies against the coronavirus that causes COVID-19 when you enrolled in the study and will be used to test your antibody levels after vaccination. About 20mL of blood (about 4 teaspoons) will be collected from your arm using a needle at these visits. These tests will not be run until after your participation in the study has ended; therefore, the results will not be available until after the study has finished and will have no effect on your taking part in the study.

Nasal swabs for COVID-19 virus detection

Nasal swabs obtained during the study (at Visit 1 and Visit 3) will be tested in a research laboratory. They will be used to detect the COVID-19 virus. The swab (which looks like a long pointed Q-tip) will be inserted into your nose and rotated 2-3 times for approximately 10 seconds, the swab will need to be inserted quite far into your nose to ensure that a good sample is taken. Your sample will not be run until after your participation in the study has ended; therefore, the results will not be available until after the study has finished and will have no effect on your taking part in the study.

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 be instructed by the study team to complete the e-Diary for 7 days after each vaccination, once a day in the evening with the first day being the day of the vaccination.

You will be given a thermometer and a measuring device to take home. You will use the thermometer to measure your temperature under your tongue and you will use the measuring device to measure any redness or swelling where the injection was given. You will need to record these measurements in the e-Diary.

The e-Diary will also ask other questions about potential side-effects you may have after the injection. If you have any severe symptoms after your vaccination, you should 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, your study doctor or nurse will contact you to check how you are.

Reporting changes to your health

It is important that you report to the study team all symptoms and side effects, whether or not you consider them to be related to the vaccine or COVID-19. If you experience any changes to your health during the study, please tell your study doctor at the earliest opportunity (eg, at your next planned visit).

Should you visit the Emergency Room or are admitted to the hospital, please contact your study doctor as soon as possible.

You will be given a Study C4591020 Emergency Contact Card. Please show this to any healthcare provider that you seek medical care from.

Phone numbers for the study team are listed in [Section 1] of this consent document.

Urine pregnancy test

If you're a woman who is able to have children, you will have a urine pregnancy test to check you are not pregnant before you get each of the 2 study injections.

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 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
- You take any new medications or receive any other vaccines
- You are going away for a long period
- You wish to take part in another research study

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

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.

If you take part in this study, the most likely risks or discomforts to happen to you are discussed below.

If you become unwell and seek medical treatment, for the purposes of the study, the study doctor may contact your usual provider, and any facility where you are treated, to obtain details and collect medical records: by signing this informed consent document, you agree to this.

Study Vaccine Risks

Up until the end of 2020, the safety of BNT162b2 has been studied in clinical trials that have included 21,744 people 16 yrs of age and older who have received at least one dose of the vaccine. In addition, since the vaccine has been approved for emergency use in many countries, about 26 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, joint aches, and muscle aches.

Common (between 1 in 10 and 1 in 100 people): feeling sick (nausea), 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, and swelling of the face or lips), pain in arm, and feeling weak or unwell.

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

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.

<u>If I catch COVID-19 disease, could the vaccine make it worse?</u>

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 to contact your study doctor if you develop symptoms that might be caused by COVID-19 (for example, fever, cough, shortness of breath).

Risks from Study Procedures

Risks and possible discomforts you 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. You may feel dizzy or may faint. If you have a previous history of feeling dizzy or fainting during blood sample collection, you should talk to the study doctor.
- **Nasal Swabs:** The risks and possible discomforts 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 you are currently pregnant, plan to become pregnant, or are breastfeeding a child, you should not join this study.

If you are able to have children and you are sexually active, you must use birth control consistently and correctly from the signing of the informed consent document until at least 28 days after you receive your last injection. This applies to men as well as women who take part in the research study. The study doctor 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.

Pregnancy Follow-up

If you or your partner become pregnant during the study, up until 1 month after your last study injection, please tell the study doctor **immediately**. Please also tell the doctor who will be taking care of you/your partner during the pregnancy that you took part in this study. The study doctor 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.

9. What are possible benefits of this study?

Vaccination with BNT162b2 has been shown to be effective in preventing COVID-19 in the groups of people already studied. However, 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.

10. What will happen to my blood and nasal swab samples?

Your blood and nasal swab 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. You will not be told of additional tests, nor will you receive results of any of these tests.

11. What other choices do I have if I do not join this study?

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

12. What happens if I am injured during this study?

If you experience a research injury, <investigator or institution name> will provide or arrange for medical treatment. BioNTech/Pfizer will cover the costs of this treatment. A research injury is any physical injury or illness caused by your participation in the study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not a research injury. There are no plans to offer you payment for such things as lost wages, expenses other than medical care, or pain and suffering. To help avoid injury, it is very important to follow all study directions. You are not giving up any of your legal rights by signing this form.

If you are treated for a research injury that is paid for by BioNTech/Pfizer, BioNTech/Pfizer or its representative will collect your name, date of birth, gender, and Medicare Health Insurance Claim Number or Social Security Number to determine your Medicare status. If you are a Medicare beneficiary, BioNTech/Pfizer will report the payment and information about the study you are in to the Centers for Medicare & Medicaid Services, in accordance with CMS reporting requirements. BioNTech/Pfizer will not use this information for any other purpose.

NOTE: All U.S. Veterans Administration sites are exempt from mandatory CMS language requirement.

13. What if I join this study and then change my mind?

If you agree to participate and then change your mind for any reason, you are free to stop participating at any time. Your decision will not affect your regular medical care or any benefits to which you are entitled. Tell the study doctor if you are thinking about stopping or decide to stop so that you can end participation in the study in the safest way.

While you are 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 mind about continuing in this study. If you decide to withdraw from the study, you may be asked to continue to participate in the study procedures even though you would no longer receive the study vaccine.

If you agree to continue with the study, information about your health will continue to be collected as described in [Section 6].

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

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

- You are unable or unwilling to follow the instructions of the study team;
- The study doctor decides that the study is not in your best interest or that you are no longer eligible to participate; or
- The study is stopped by BioNTech/Pfizer, the 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.

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

14. What will I have to pay for if I take part in this study?

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

15. Will I be paid for taking part in this study?

You will not receive any payment for taking part in this study. However, for each visit you complete, you will be reimbursed by the study site to cover reasonable expenses (for example, parking, meals, travel) that you have as a result of taking part in this study. You 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 they may make a profit. There are no plans to pay you or provide you with any products developed from this research. BioNTech/Pfizer will own all products or processes that are developed using information from the study.

16. What will happen to my personal information?

The study team will give you a Privacy Supplement, which is considered part of this consent document. The Privacy Supplement tells you about:

- What personal information may be collected from you during the study;
- How your personal information will be used and by whom (including by the study site, BioNTech/Pfizer, and others outside the study site);
- How your biological samples and images will be handled (if collected);
- How your personal information might be used for other research;
- How your personal information will be protected during transfer;
- Your data protection rights, and whom you may contact about these rights or any related concerns or complaints; and
- What happens to your personal information if you decide to stop taking part in the study.

17. 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 you. 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.

These Web sites 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 individual study results may be given to you or your doctor (if different from the study doctor) in accordance with applicable law, but will not be given to your 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 individuals, including you. BioNTech/Pfizer does not plan to return information from any exploratory research to you, the study doctor, or your doctor (if different from the study doctor).

18. Signatures

Agreement to Participate and to Process Data
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 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 personal information, as explained in the Privacy Supplement. I understand and agree to the processing of my personal information within and outside my country of residence for health care, medical research and/or regulatory purposes.
3. I understand that taking part is voluntary and that I am free to stop taking part in this study or to withdraw my consent to the processing of my personal information at any time. I do not need to give any reason and my regular medical care and legal rights will not be affected. However, even if I withdraw my consent to processing, my 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 biological samples may not be able to be destroyed because they may no longer be traceable to me, may have already been used, or may have been given to a third party.
4. I agree to the study team accessing my medical history, including information from medical records and test results and any medical treatment I receive during the course of the study, and if necessary, contacting my doctor or any other health care providers treating me for access to such information.

5. I understand that BioNTech/Pfizer and/or others working with or on behalf of BioNTech/Pfizer, institutional review boards (IRBs) or independent ethics committees (IECs), and regulatory agencies may need access to personal information about me 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 personal information.
6. I do not give up any of my legal rights by signing this consent document. I have been told that I will receive a signed and dated copy of this document.
7. I agree to take part in the study described in this document.

_____
Printed name of participant

_____ _____
Signature of participant Date of signature§
(If no legally acceptable representative is used)

§ Participant must personally date their signature.

Person Obtaining Consent:

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Conducting the Consent Discussion † Date of signature

† 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 signs the consent document.

PRIVACY SUPPLEMENT

This Privacy Supplement describes how we will collect, use, and share your personal information. It also describes your privacy rights.

You are not required to authorize the use and disclosure of your personal information as described below. If you do not agree, you cannot participate in this study, but there will be no penalty or change to your regular medical care or payment for that care.

A. What personal information may we collect about you during this study?

Your study team and others assisting with your study-related care will collect or provide information about you, some of which is sensitive. This information may include:

- **Information that directly identifies you** such as your name, address, telephone number, email address and date of birth.
- **Sensitive personal information** such as your medical history, data from this study (including study results from tests and procedures), demographics (for example, age and gender) and other sensitive information that is needed for this study such as HIV status, race and ethnicity.
- **Data from testing and analysis of biological samples** (such as blood or urine) **and images** (such as X-rays, CT-Scans, and medical photographs). This may also include genetic information.
- **Data captured from electronic devices** if you complete the consent process using the eConsent tablet or if you use a mobile application or other digital tool during the study. This information may include data about your use of the eConsent tablet, application or tool, such as the length of time it takes you to complete the consent process, the number of times you scroll between pages or click on the hyperlinked items, and your electronic signature. Mobile applications and other digital tools used in the study may have their own privacy policies. Those policies provide additional information about the data processing activities performed by the digital tools.

B. Who will use my personal information, how will they use it, and where will it be stored?

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. The study team must keep your personal information private. A U.S. privacy law called HIPAA (the Health Insurance Portability and Accountability Act of 1996) protects the privacy of your personal health information. **[Name of Covered Entity]** must get your permission to use and share with others any personal health information that could identify you.

Your personal information will be accessed by:

- Your study doctor and other study team members;
- BioNTech/Pfizer and its representatives (including its affiliated companies);
- People, or organizations providing services for, or collaborating with, BioNTech/Pfizer;
- Any organization that obtains all or part of BioNTech's/Pfizer's business or rights to the product under study;
- Government or regulatory authorities (including the U.S. Food and Drug Administration and authorities in other countries); and
- Institutional Review Board(s) (IRB) or Independent Ethics Committee(s) (IEC) overseeing this study.

The individuals and groups listed above will use your personal information to conduct this study, and to comply with legal or regulatory requirements, including to:

- determine if you are eligible for this study;
- **[**include as applicable: provide you with reimbursement, as allowed by the study, for your time, effort and certain expenses related to your participation;**]**
- verify that the study is conducted correctly and that study data are accurate;
- answer questions from IRB(s), IEC(s), or government or regulatory agencies;
- assess your use of electronic devices in the study, for example, to determine how long it takes you to complete any e-consent module used for the study and your comprehension of the e-consent process;
- contact you during and after the study (if necessary);
- follow-up on your health status, including using publicly available sources should the study team be unable to contact you using information held on file;
- protect your vital interests or the interests of your pregnant partner (for example, a critical medical situation, such as providing information to an emergency department of a hospital where you are being treated); and
- answer your data protection requests (if any).

The study site will retain your personal information for the period necessary to fulfill the purposes outlined in the consent document(s), which could be up to 15 years after the end of the study OR unless a different retention period is required or permitted by law].

If you provide someone else's personal information (for example, an emergency contact or details of family medical history) you should make them aware that you have provided the information to us. We will only use such personal information in accordance with this informed consent and applicable law.

C. What happens to my personal information that is sent outside the study site?

[Name of Covered Entity] is required by HIPAA to protect your personal information. After your information is shared with others, such as BioNTech/Pfizer, it may no longer be protected by HIPAA.

Before the study team transfers your personal information outside the study site, the study site will replace your name with a unique code. We call this "**Coded Information**." The study site will keep the link between the code and your personal information confidential, and BioNTech/Pfizer will not have access to that link. BioNTech/Pfizer employees and representatives are required to protect your Coded Information and will not attempt to re-identify you.

Your Coded Information will be used by the following:

- BioNTech/Pfizer and its representatives (including its affiliated companies);
- People and/or organizations providing services to or collaborating with BioNTech/Pfizer;
- Any organization that obtains all or part of BioNTech/Pfizer business or the rights to the product under study;
- Other researchers;
- The IRB or IEC that approved this study; and
- Government or regulatory authorities;

The above parties may use your personal information for the following purposes:

- **Conducting the study**, including:
  - Examining your response to the study vaccine;
  - Understanding the study and the study results and learning more about COVID-19; and
  - Assessing the safety and efficacy of the study vaccines.
- **Complying with legal and regulatory duties** such as:
  - Ensuring the study is conducted according to good clinical practice;
  - Making required disclosures to IRB(s), IEC(s), or government or regulatory authorities;
  - Seeking approval from government or regulatory authorities to market study vaccine (it is possible that these government or regulatory authorities may disclose your Coded Information to other researchers for the conduct of future scientific research); and
  - Sharing study data with other researchers not affiliated with BioNTech/Pfizer or study team (including through publication on the internet or other ways. However, information that could directly identify you will not be made available to other researchers).

- **Publishing summaries of the study results** in medical journals, on the internet or at educational meetings of other researchers. You will not be directly identified in any publication or report of the study. But some journal representatives may need access to your Coded Information to verify the study results and ensure the research meets the journal's quality standards. Also, journals may require that genetic and other information from the study that does not directly identify you be made available to other researchers for further research projects.
- **Improving the quality, design and safety** of this study and other research studies.

BioNTech/Pfizer will retain your Coded Information for the period necessary to fulfill the purposes outlined in the consent document(s), [Insert one of the following options as appropriate: which could be up to [insert local requirements; e.g., 25 years] after the end of the study, OR unless a different retention period is required or permitted by law].

D. How are my biological samples and images handled?

If biological samples or images of you are taken during the study, those samples and images will be handled in the same way as your Coded Information. All samples will be treated as required by law. Sometimes your study site may be unable to remove information that can identify you from your images before sending images to BioNTech/Pfizer and its representatives.

E. Can my personal information be used for other research?

Your Coded Information may be used to advance scientific research and public health in other projects that will occur in the future. At this time, we do not know the specific details of these future research projects.

This other research may be conducted (1) in combination with data from **other sources**, (2) for **additional scientific research purposes** beyond objectives of this study, and (3) subject to **specific safeguards**.

- **Other sources**: Coded Information may be combined with data from other sources that are taken from outside typical research settings. These sources may include: coded electronic health records, claims and health care cost and payment data or databases, product and disease registries, data gathered through your phone, tablet, or other devices and mobile applications, social media, pharmacy data, biobanks, or patient engagement programs.
- **Additional scientific research:** Coded Information may be used to understand how to make new medicines, devices, diagnostic products, tools and/or other therapies that treat diseases and to improve future research. It may also be used to inform value, cost-effectiveness and pricing, and to optimize access to medicines.
- **Specific safeguards** will be used to protect your Coded Information, which may include:

- Limiting access to Coded Information to specific individuals who will be obligated to keep this information confidential and will be prohibited from attempting to re-identify your Coded Information.
- Using security measures to avoid data alteration, loss and unauthorized access.
- Anonymizing the data by removing and/or replacing information from the Coded Information and/or destroying the link to the Coded Information.
- Assessing data protection systems to identify and mitigate privacy risks, if any, associated to each additional scientific research purpose.
- When required by applicable law, ensuring that the scientific research has the approval of IECs, IRBs, or other similar review groups.

F. How will my personal information be protected when transferred from the study site to BioNTech/Pfizer?

Your personal information will be treated in compliance with applicable data protection laws, including requiring people and/or organizations providing services to or collaborating with BioNTech/Pfizer to use appropriate measures to protect the confidentiality and security of your personal information. Some of the people using your personal information, including your Coded Information, may be based in countries other than your country. Data privacy laws may be different in these countries. If your personal information is transferred by BioNTech/Pfizer to other countries, BioNTech/Pfizer, and people working with BioNTech/Pfizer, will take steps to maintain the confidentiality of your personal information.

G. What are my data protection rights? Whom may I contact about these rights or any concerns or complaints?

You have the right to access your personal information that is held about you by the study team. *To ensure the integrity of the study, you will not be able to review some of the data until after the study has been completed.*

If you wish to exercise this right or have concerns about how your personal information is being handled, it is best to contact the [Institution] and not BioNTech/Pfizer. Generally, BioNTech/Pfizer will not know who you are (by name) because BioNTech/Pfizer usually holds only your Coded Information, which does not include your name or other information that can easily identify you. To contact the [Institution] or the study team representative, please see the **contact information at [Section 1]** of the consent document.

H. What happens if I do not wish to continue with the study?

As noted in the main consent document, you are free to stop taking part in this study at any time by telling the study team. Your authorization for the study site to disclose your personal information does not expire unless you withdraw your authorization.

If you stop taking part in the study and you do not tell the study team, your contact information may be used by the study team to contact you and check whether you wish

to continue in the study. If the study site is unable to reach you, BioNTech/Pfizer may use publicly available records about your health to monitor the long-term safety of the study drug. This will only be done if allowed by the law.

If you stop taking part in the study but do not withdraw your consent, your personal information will continue to be used in accordance with this Privacy Supplement and applicable law. No new information or samples will be collected about you or from you by the study team, unless you have agreed to provide them.

If you decide to withdraw your consent:

- You will no longer be able to participate in the study;
- No new information or samples will be collected about you or from you by the study team;
- The study team may still need to report any safety event that you may have experienced due to your participation in the study to BioNTech/Pfizer;
- Your personal information, including Coded Information, that has already been collected up to the time of your withdrawal will be kept and used by BioNTech/Pfizer to guarantee the integrity of the study, to determine the safety effects of the study vaccine, to satisfy legal or regulatory requirements, and/or for any other purposes permitted under applicable data protection and privacy laws;
- Your personal information (including Coded Information) will not be used for further scientific research. However, if your personal information has been anonymized so that the information does not identify you personally, that information may continue to be used for further scientific research (as described in Section E of this Privacy Supplement), as permitted by applicable law; and
- Biological samples that have been collected but not analyzed will no longer be used, unless permitted or required by applicable law.

You have the additional 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. The study team will then send your coded request to BioNTech/Pfizer. Laws or regulations may require that your samples be destroyed or de-identified if you withdraw from the study, regardless of whether you specifically make such a request.

However, we cannot guarantee the destruction of samples because the sample may no longer be traceable to you, they may have been used up, or they may have been released to a third party. In those cases, it would not be possible to remove and destroy your biological samples and any related data.