INFORMED CONSENT FORM AND HIPAA AUTHORIZATION

TITLE: A PHASE 3 MASTER PROTOCOL TO EVALUATE ADDITIONAL DOSE(S) OF BNT162b2 IN HEALTHY INDIVIDUALS PREVIOUSLY VACCINATED WITH BNT162b2

PROTOCOL NO: C4591031
IRB Protocol # 20212483

SPONSOR: BioNTech. Pfizer is conducting the study for BioNTech

INVESTIGATOR: Donald Martin Poretz, MD
3289 Woodburn Rd
Suite 250
Annandale, Virginia 22003
United States

STUDY RELATED PHONE NUMBER(S): 703-560-4821 (24 hours)

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 is possible that you may 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 the right decision 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 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 taking part in this study.

Each and every person plays a powerful role in clinical research
Every approved medicine and vaccine we have today was tried and tested in a clinical study. With your participation, and the help of countless others, we are working toward developing therapies to improve the lives of people worldwide. From all of us dedicated to that goal at BioNTech/Pfizer, thank you for your interest in this research. We could not do it without you.

Brief Summary of 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/study site 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 started to look for treatments and ways to prevent COVID-19 including companies like BioNTech/Pfizer who make vaccines.

Since December 2020 a number of countries have authorized the emergency use of a number of COVID-19 vaccines to prevent COVID-19. This includes the investigational Pfizer-BioNTech COVID-19 Vaccine (BNT162b2).

Vaccines help your body to produce antibodies to help you to fight off a disease. This research study involves an investigational vaccine (BNT162b2) to prevent COVID-19, that will be given to volunteers. “Investigational” means that the study vaccine is currently being tested. It is not approved by the FDA, although it does have Emergency Use Authorization (EUA).

You have already taken part in a study that looked to see if the BNT162b2 vaccine helps to prevent adults and children getting COVID-19. **The purpose of this study is to see if a booster dose of BNT162b2 vaccine is needed and how well a booster dose of the BNT162b2 works in people who are 16 years or older and have already had 2 vaccinations of BNT162b2 at least 6 months ago.**

If you decide to join the study, the study team will assess if you are eligible to take part. If you are eligible to take part you will be given 1 vaccination of either COVID-19 Vaccine BNT162b2 or placebo. If the study results suggest that a booster dose is needed, people who were given the placebo will be offered a booster dose. The decision to give a booster dose to the people who had placebo will be based on information learned during this study. There is no fixed time when this decision will be made and there is no guarantee that the people who are given placebo will be offered a booster dose, if it turns out to not be necessary.

The investigational vaccine, called BNT162b2, is an 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.

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 then end of April 2021 about 400 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,
- diarrhea,
- joint aches,
- muscle aches,
- feeling sick (nausea),
- throwing up (vomiting),
- injection site redness,
- enlarged lymph glands,
- allergic reaction (symptoms may include rash, itching, hives, and swelling of the face or lips),
- decreased appetite,
- lack of energy,
- sweating and night sweats,
- pain in arm,
- feeling weak or unwell, and
- severe allergic reaction (anaphylaxis).

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 you have 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.

This research study is different from, and does not replace, 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. As

such, if you take part in this study you may have additional visits, procedures, extra laboratory tests, and/or follow a modified treatment plan. 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). It is up to you to decide if you want to take part in this study. You can choose not to take part in the study or to take part now, and then change your mind later at any time without any penalty or losing any benefits or medical care to which you are otherwise entitled. You can ask the study doctor or study team any questions you have before you decide whether you want to take part in this study. 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.

Your personal information will be protected during this study in the manner described in the accompanying **HIPAA Authorization**.

This study has been reviewed by the Institutional Review Board (IRB) (a group of people who review the study to protect your rights).

If you decide to take part, the first thing you will be asked to do is to sign and date this informed consent document. You will get a copy of the signed and dated consent document to take home. Please keep this consent document for your reference.

About the Study
Number of Study Participants
There will be about **10,000** people taking part in this study in **US and other countries**.

About 6000 people between the ages of 16 and 55 years old will take part and about 4000 people 56 years and older will take part.

For every 1 person that is given a COVID-19 Vaccine (BNT162b2) booster dose at the first visit there will be 1 person that is a given a placebo vaccine (a placebo vaccine does not contain any activate ingredients; in this study the placebo will be salt-water, also known as normal saline).

Length of Study for Participants.
People taking part will be in this study who are given COVID-19 Vaccine (BNT162b2) will be in the study for about **1 year** and will need to visit the research site at least **2**

times and have 2 follow-up phone contacts about 1 month and 12 months after the COVID-19 vaccination.

The length of time people who are given placebo will be in the study depends on the information (results) that are gathered during the study. **The team from Pfizer** will look at the information at regular intervals to see if a booster dose is needed. If a booster dose **is not needed** people who are given placebo will be in the study for about a year, will visit the research site at least **2** times and will have 2 follow-up phone contacts about 1 month and 12 months after they started the study. If a booster dose **is needed** these people will be contacted and will remain in the study for about 6 months after their booster COVID-19 vaccination. The tables below give more information about the study visits.

Process for Selecting Study Participants
After you sign and date this consent document, the study team will assess if you are eligible to take part. If you do not meet the study requirements, you will not be able to take part. The study doctor will explain why and discuss other options with you, if available. If you meet the study requirements, you will be able to take part in the study. A description of the study vaccine, study assignment, and procedures for this study are described below.

Study Vaccine and Assignment
Once the study doctor has confirmed you meet the study requirements, you will be randomly assigned (like flipping a coin) to receive the COVID-19 Vaccine (BNT162b2) booster dose or placebo. For every 1 person who receives the COVID-19 Vaccine (BNT162b2) 1 person will receive the placebo. No one (including you, your personal doctor and the study team) can choose this assignment.

This is an ‘observer-blind study’, which means that you and the study doctor will not know whether you are receiving the study COVID-19 Vaccine or placebo injection, but the person who gives you the injection will know because the COVID-19 Vaccine and placebo do not look the same. The person that gives you the injection will not be able to talk about it with you. In case of urgent need, the study doctor can learn quickly whether you have received COVID-19 Vaccine or placebo.

The COVID-19 Vaccine or placebo will be given to you through an injection into the muscle in your upper arm. On the day you receive the injection, you will be asked to wait at the study site for at least 30 minutes for observation.

During the study, the Pfizer study team will look at the information they have collected (results) and see if the protection against COVID-19 is different in those people who

received the booster compared to those that received the placebo. If you are assigned to the placebo group and the protection in those people that received the booster dose is better, you will be told and offered a booster yourself.

Post-Study Access to the Study Vaccine
The study vaccine booster dose will be given to you only during this study and not after the study is over.

Study Tests, Procedures and Assessments
In this research study, you will have certain tests, procedures, and assessments. A brief overview is provided below. The study doctor may ask you to come in for additional tests, procedures, and assessments, if necessary, to protect your health.

Visit Description	Visit 1	1-Month Follow-up PHONE CALL	6-Month Follow- up Visit	12-Month Follow- up PHONE CALL
Review, sign, and date informed consent document	✓			
Answer questions about your health, including any medicines and vaccinations that you are or have taken	✓	✓	✓	✓
Take a swab from your nose (nasal swab)	✓			
Blood sample				
Your temperature will be measured	✓			
Physical examination, if needed	✓			
Height and weight measured	✓			
Urine sample for pregnancy test, if applicable	✓			
Vaccination (BNT162b2 booster dose or placebo)	✓			
E-diary training	✓			
Complete illness e-diary at least weekly	✓			
Contraceptive use (if appropriate)	✓	✓		
Return your e-diary or delete the app				✓

If you are assigned to the placebo group and it is decided that you need a booster dose of COVID-19 vaccine you will be informed and you will have the following visits.

Visit Description	COVID-19 booster dose for people who were given placebo	1-Month Follow-up PHONE CALL	6-Month Follow- up PHONE CALL
Answer questions about your health, including any medicines and vaccinations that you are or have taken	✓	✓	✓
Take a swab from your nose (nasal swab)	✓		
Blood sample	🩸		
Your temperature will be measured	✓		
Urine sample for pregnancy test, if applicable	✓		
Vaccination (BNT162b2 booster dose)	✓		
Complete illness e-diary at least weekly		✓	
Contraceptive use (if appropriate)	✓		
Return e-diary or delete the app			✓

COVID Illness e-diary

At your first visit, you will either be given an “e-diary” (similar to a mobile phone), or you will download an e-diary application (‘app’) to your smart phone if you have one. You will also be given a thermometer. The study team will provide training on how to use the e-diary and thermometer.

The e-diary has questions related to any potential COVID-19 symptoms that you have.

You will need to complete the COVID-19 illness e-diary once a week for the whole time you are in the study, or until your study doctor tells you that you no longer need to complete it, to report if you have any COVID-19 symptoms or not. You will also need to complete the COVID-19 illness e-diary if you have COVID-19 symptoms outside of the weekly question.

You may receive alerts to the device or your own smartphone to remind you to complete the e-diary.

The e-diary is secure, and your confidentiality will be maintained.

If You Have COVID-19 Symptoms

If you have any of the following symptoms at any time while you are in the study, you must contact the study doctor immediately.

Note that this is not instead of your routine medical care. If you feel unwell enough that you would normally see a healthcare professional, please contact your usual provider, as well as the study doctor.

- A diagnosis of COVID-19
- Fever
- New or increased cough
- New or increased shortness of breath
- Chills
- New or increased muscle pain
- New loss of taste/smell
- Sore throat
- Diarrhea
- Vomiting

Potential COVID-19 Illness Visit (Telehealth or In-Person Visit)	
Answer questions about your health, including medications, treatments, or if you have sought medical care	✓
Take a swab from your nose	✓
The study team will collect information about your COVID-19 like illness	✓

If you have an in-person visit the site staff will take a swab from your nose. If you have a telehealth visit (telephone or video call) you will need to take a swab from your nose yourself. The swab is to check for the coronavirus.

We will give you separate instructions about how to take a nose swab yourself and how to send the swab to the study doctor. The result from this nose swab will be provided to the study doctor once it is available, but this will take some time, and cannot be used to diagnose if you have COVID-19. This is why it is important that you contact your usual provider if you have COVID-19 symptoms and think you need medical care.

If you are diagnosed with COVID-19 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**.

What happens if you have a positive nose swab test result?
Results from all nose swab tests will be provided to your study doctor, however this will take some time so you should not rely on these results for medical treatment. As we will be unable to inform you of a positive result in real time, if you think that you may have COVID-19, you should seek care/a test from your usual provider.

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

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

Your blood samples
Everyone in the study will need to give 2 or 3 blood samples. The blood samples will be approximately 20 mL of blood (about 4 teaspoons), see tables above () for time points when blood samples are given.

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

What will happen to my blood and nose swab samples?
Your blood and nose 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. No testing of your DNA will be performed.

Possible Risks and Discomforts
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 experience any of the potential side effects described below and think they could temporarily affect your ability to drive or use machines, you should not do so.

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

It is important that you report to the study team all symptoms and side effects as soon as they occur. Phone numbers for the study team are listed on page one of this consent document.

Study Vaccine Risks
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 you have any of the following symptoms after receiving the vaccine:

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

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

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 you have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart) previously, please tell your study doctor.

As 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 you experience as soon as they occur, whether or not you think they are caused by the study vaccine.

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

If I catch COVID-19 disease, could the vaccine make it worse?
For some other vaccines tested in animals against similar viruses (but not the coronavirus that causes COVID-19), there have been reports of the illness being more severe in the animals that received the vaccine than in those that did not. So far this has not been seen with BNT162b2. 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).

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

All drugs have a potential risk of causing an allergic reaction, which (if not treated quickly) could become life-threatening. You should get medical help right away or call your local emergency number and contact the study doctor if you think you have any of the following symptoms of a serious allergic reaction: trouble breathing or swelling of the face, mouth, lips, gums, tongue, or neck. Other allergic reactions may include rash, hives, or blisters.

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

Risks 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.
- **Nose swabs:** The risks and possible discomforts involved in taking nose swabs may include pain or general discomfort. Sometimes it may cause the nose to bleed.

Pregnancy-Related Risks; Use of Birth Control

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

If you are currently pregnant, plan to become pregnant, or are breastfeeding a child, you cannot be in this study.

If you are able to have children and you are sexually active, you must use birth control consistently and correctly for at least 28 days after you receive your last vaccination. **This applies to men and women who take part in this 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.

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

Pregnancy Follow-up

If you or your partner become pregnant during the study, up until 28 days after your last vaccination, 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.

Possible Benefits of Participation

If you decide to participate and the study vaccine booster is effective for you, your chances of getting COVID-19 may be reduced. Vaccination with BNT162b2 vaccine has been shown to work in preventing COVID-19 in the groups of people already studied however it is not known how long this protection may last. The booster may improve the level of protection – if that is shown to be the case, everyone in the study will receive the booster at some point. In addition, information learned from the research study may help other people in the future.

You still need to follow local recommendations about how to avoid COVID-19 (for example, social distancing and mask use).

Other Options Instead of this Study

This study is for research purposes only. Your alternative is to continue in the current study you are in and not take part in this study.

Participant Responsibilities & Rights

Special Instructions for Study Participants

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

- ✓ You have received a COVID-19 vaccine or are taking any medication to prevent COVID-19
- ✓ You don't understand anything about the study
- ✓ You are not able to comply with the study requirements
- ✓ There are changes in your health, or if you have to visit a health care provider
- ✓ Your e-diary device or app is not working properly
- ✓ You take any new medications or receive any other vaccines
- ✓ You are going away for a long period
- ✓ You are going to move to a new house
- ✓ You wish to take part in another research study
- ✓ You previously took part in this study, have been in any other study in the past 28 days, or are currently involved in any other study.

It is important that you:

- ✓ Call the study doctor or study staff if you have any COVID-19 symptoms, even if they are mild.
- ✓ Follow the instructions you are given by the study doctor and study team.

- ✓ Do not take part in any other study without approval from the study doctor. Taking part in more than one study at the same time could put your safety at risk.
- ✓ Take part in the study only at this location. Participating in this study at more than one study site could put your safety at risk.
- ✓ Tell other doctors, nurses, and health care providers about your participation in this study by showing the information card provided to you by the study team.

Process for Participants Who Wish to End Study Participation.
You can stop being in the study at any time. Your decision will not affect your regular medical care or any benefits to which you are otherwise entitled. Tell the study doctor if you decide to stop so that you can end participation in the safest way. The study doctor will explain what other steps may occur.

While you are participating, the study doctor will tell you in a timely manner if new information is learned that could change your mind about being in this study.

The study doctor or BioNTech/Pfizer may also decide to take you off the study vaccine and/or remove you from the study (even if you do not agree) in the following situations:

- You are unable or unwilling to follow the instructions of the study;
- The study doctor decides that the study is not in your best interest or that you are no longer eligible to be in the study; or
- The study is stopped by BioNTech/Pfizer, an Institutional Review Board (IRB) or independent Ethics Committee (IEC) (a group of people who review the study to protect your rights), or by a government or regulatory agency such as the U.S. Food and Drug Administration (FDA).

Information about your health will continue to be collected and used as described in this document.

You may request that any samples that have been collected from you as part of the study be destroyed, and in some countries, local laws or regulations may require that your samples be destroyed regardless of whether you specifically make such a request. However, we cannot guarantee the destruction of samples because, for example, the samples may no longer be traceable to you or the samples may have been used up.

Study-Related Injuries
You will also be given a card with important emergency contact information, including a 24-hour phone number. Show this card to any health care provider if you seek emergency care during this study. This card includes information about the study that will help the health care provider treat you.

If you are injured or get sick because of being in this research, call the study doctor immediately. If you experience a research injury, your study doctor 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.

Costs for Study Participants
You will not have to pay for the study vaccine (BNT162b2 booster dose or placebo) or study-related procedures and visits.

Talk to the study doctor if you have any questions about costs resulting from participating. You or your insurance company may have to pay for routine care you would receive whether or not you are in the study. You may talk to the study staff and your insurance company about what is covered.

Payment for Taking Part in the 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 paid $5.00 for each weekly illness diary completion for the duration of the study. You will be reimbursed $119.00 by the research site for each visit you complete to cover your out-of-pocket expenses related to this study, such as travel and parking. You will receive $10.00 for completed phone visits. You will receive reimbursements after each visit.

Some reimbursements will involve using a third-party vendor, working on behalf of BioNTech/Pfizer. This vendor will support the reimbursement process. In order to do this, you will need to provide the vendor with certain personal information. This information may include your Subject ID, Name, Address, and Date of Birth along with

other information. This information will be collected from you by the site staff and provided to the vendor. If you choose not to provide this information, a different method of reimbursement will be made available to you.

Reimbursement received as compensation for participation in research is considered taxable income. If payment exceeds $600 in any one calendar year, the vendor will file a 1099 (Miscellaneous Income) form on behalf of BioNTech/Pfizer. The vendor will need your Name, Address, and Social Security Number.

What if Something is Developed from this Research?
BioNTech/Pfizer may use information and biological samples resulting from the study to develop products or processes from which it may make a profit. There are no plans to pay you or provide you with any products developed from this study. BioNTech/Pfizer will own all products or processes that are developed using information and/or biological samples from the study.

Maintaining Confidentiality and Use of Medical and Research Records
All information that you give will be kept strictly confidential. However, absolute confidentiality cannot be guaranteed because of the need to share your study-related information with others.

Medical and research records collected during this study will be stored by the study team at your study site and may also be stored on a third-party cloud-based platform paid for by BioNTech/Pfizer. These medical and research records will be reviewed to verify that clinical trial procedures and/or data are correct.

Your medical and research records may 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 [FDA] and those located in other countries; and
- Institutional Review Board(s) (IRB) or Independent Ethics Committee(s) (IEC) overseeing this study. The IRB is a group of scientists and non-scientists who review the ethics of research. The goal of the IRB is to protect the rights and welfare of study participants.

These people may look at your records to make sure the study has been done the right way. They also want to make sure that your health information has been collected the right way, or for other reasons that are allowed under the law.

In order to keep records that identify you confidential, the study site will replace your name with a unique code. The records and information labelled with the code are called "**Coded Information**." The study site will keep the link between the code and your name confidential. Your information will be transferred to BioNTech/Pfizer using the unique code assigned to you. BioNTech's/Pfizer's employees and those with whom your Coded Information is shared are required to protect your Coded Information and will not attempt to re-identify you.

Your personal information will be collected, used, and shared (together called "processing") in compliance with applicable privacy laws.

If information about this study is published, you will not be identified.

There is a risk of loss of confidentiality in research studies. Every effort will be made to protect you and your health information to the extent possible.

You will also be provided a separate HIPAA Authorization that further describes how your information, biological samples, and/or images will be processed and your privacy rights.

Under certain circumstances, information that identifies you by name may leave the study site in connection with the study and be sent to a vendor contracted by BioNTech/Pfizer, in order to:

- support the use of digital tools (e.g. electronic consent, mobile applications) in the study
- provide you with reimbursement, as allowed by the study, for your time, effort and certain expenses related to your participation

- The people and/or organizations contracted by BioNTech/Pfizer to provide these services must keep your personal information private, and they will not share with BioNTech/Pfizer any information that can directly identify you.

There may be times when additional information about your medical tests, any hospitalizations, or a medical event that has occurred to you during the study will need to be sent to a committee engaged by BioNTech/Pfizer to assess the research study's progress, safety, and, if needed, to see if the study vaccine is working. These committees might include a data safety monitoring committee, or an adjudication committee, are separate from the study site, and may be located outside your

country. Any directly identifying information, such as your name, will be removed on all medical and research records sent to this committee through this process.

Contact Information and Links to Additional Study Information
The study team will address any questions, concerns, or complaints you may have before, during, and after you complete the study. Contact information for your study site and study doctor is listed on the first page of this document.

If you think this research has hurt you or made you sick, talk to the research team. Phone numbers for the study team are listed above on page one of this form.

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.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at 1-855-818-2289 or Researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research participant.

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 and https://www.clinicaltrialsregister.eu/.

The website mentioned in this section is in English only. If you need assistance to understand the content in a different language, 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).

Signatures

I have had enough time to read this consent document and have had the opportunity to ask questions. All of my questions have been answered to my satisfaction. I have been told that my participation is voluntary and I can withdraw at any time. I agree to take part in the study. I have been told that I will receive a copy of this signed and dated document.

Printed name of participant	
Signature of participant	Date of signature (dd-Mmm-yyyy)§

§ 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 consent discussion (dd-Mmm-yyyy) †

† The investigator, or an appropriately qualified and trained person designated by the investigator to conduct the informed consent process, must sign and personally date the consent document.

Thank you for your participation

Your participation in this study matters. Your study team is here to support you throughout your journey with us, and we at BioNTech/Pfizer want to sincerely thank you for your time and commitment to this research.

HIPAA AUTHORIZATION

A U.S. privacy law called HIPAA (the Health Insurance Portability and Accountability Act of 1996) protects the privacy of your personal information held by most health care providers. The study site must get your permission (called an "authorization") to use and share with others for research purposes any personal information that could identify you.

This Authorization describes how the study site and BioNTech/Pfizer will collect, use, and share your personal information.

This Authorization 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 to do so, you cannot participate in this study, but there will be no penalty or loss of benefits to which you are otherwise entitled or change to your regular medical care or payment for that care.

The study site is required by HIPAA to protect your personal information. By signing this form, you authorize the study site to use and share your personal information as described below. After your personal information is shared with others, such as BioNTech/Pfizer and individuals and groups listed below, it may no longer be protected by this HIPAA and may be re-disclosed to other third parties as described in this Authorization and in the main consent document. These groups are committed to keeping your health information confidential.

What information may be collected about you during this study?
In order to conduct the study and comply with legal and regulatory requirements, your study team will collect information about you. Information about you may include information that directly identifies you, demographics, and sensitive information such as your medical history, medical records and data from this study (including study results from tests, any physical exams, and procedures, diagnoses, treatment, sex, race, and

ethnicity), demographics (for example, age and gender) and other sensitive information that is needed for this study such as HIV status. If required by this study, the study team may also collect biological samples from you and take images or make audio/video recordings of you.

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

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

How will your information be used and how long will it be used?
Any information collected about you during this study will be entered into records, including health records, maintained by the study team at your study site. The site will retain your information for the period necessary to fulfill the purposes outlined in this Authorization, in the main consent document, and/or for the maximum period permitted by applicable law which could be at least 15 years after the end of the study.

Your information may be accessed and used by:

- The study team;
- BioNTech/Pfizer (including its affiliated companies) and its representatives, for example, study monitors and auditors;
- People and/or organizations providing services to or collaborating with BioNTech/Pfizer;
- Any organization that has or obtains rights to the product under study or that obtains all or part of BioNTech/Pfizer's business;
- Other researchers, including researchers involved in the study at sites other than the one at which you are participating in the study;

- Institutional Review Board(s) (IRB) or Independent Ethics Committee(s) (IEC) overseeing this study.
- Government or regulatory authorities, including the United States Food and Drug Administration (FDA) and authorities located in other countries.

Typically, your name will be removed from your information before it is sent outside the study site. As described in the main consent document, your name will be replaced with a unique code before your information (and/or your biological samples, images and/or audio/video recordings, if collected as part of the study) leaves the study site. This information is referred to as your "Coded Information". Data generated using biological samples, images and/or audio/video recordings of you, if collected during the study, will be handled in the same way as your Coded Information, unless otherwise stated in this Authorization or the main consent document. Sometimes the study site may be unable to remove information that can identify you from your images, meaning that the images shared with others may be identifiable as yours.

The study site will upload your information, including information that directly identifies you, to a designated secure electronic system maintained by a third party engaged by BioNTech/Pfizer. BioNTech/Pfizer and/or BioNTech's/Pfizer's representatives will use this secure system to review and verify study data as they would at the study site. Some of these uploaded records will be kept for the period necessary to fulfill the purposes outlined above and in the main consent document, as required by applicable law and/or for the maximum period permitted by applicable law on the secure electronic system. The remaining records that are uploaded will be temporary and removed/deleted from the secure electronic system after the study is over.

The individuals and groups listed above will use your information, including your Coded Information, to:

- conduct this study;

- comply with legal or regulatory requirements, including for all of the purposes listed in the main consent document that you were provided and to seek approval from government or regulatory agencies to market the study vaccine;
- determine if you are eligible for this study;
- verify that the study is conducted correctly, and that study data are accurate;
- answer questions from IRB(s) or government or regulatory agencies (such as the FDA);
- publish the results of studies;
- contact you during and after the study (if necessary);
- 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
- improve the quality, safety, and design of this study and other research studies.

BioNTech/Pfizer may also be required to provide information gathered from this study, including your Coded Information, to regulatory authorities (such as the FDA) for public disclosure. In such cases, BioNTech/Pfizer will take steps to minimize the risk that you could be re-identified. BioNTech/Pfizer will retain your Coded Information for the period necessary to fulfill the purposes outlined in this Authorization and in the main consent document, and for the maximum period permitted by applicable law after the end of the study.

Can your Coded Information, biological samples, images, and/or audio/video recordings, if collected as part of the study, be used for other research?

Yes. BioNTech/Pfizer may use your Coded Information, biological samples, images and/or audio/video recordings, if collected as part of the study, in the future to support and advance other scientific research projects, including improving the quality, design, and safety of other

research studies, research supporting public health aims, and developing medicines, vaccines, diagnostic products, and tools.

At this time, we do not know the specific details of these research projects; however, your Coded Information, biological samples, images and/or audio/video recordings could be used in combination with data from other sources, not related to you or this study.

Reasonable safeguards will be used to protect your Coded Information, biological samples, images and/or audio/video recordings used in any future research and may include: (a) limiting access to individuals bound by duties of confidentiality; (b) taking steps to minimize the risk that you could be re-identified; and (c) obtaining approval of ethical review boards. Furthermore, if your Coded Information, biological samples, images and/or audio/video recordings (if collected as part of the study) have identifiers removed such that they can no longer readily be identified with you, they may be used for future research purposes.

What are your rights to your personal information?
You may have the right to access your personal information that is held by the study site.

However, by signing this authorization, you agree that your right to access certain of your information held by the study site will be suspended until after the study is over. After the study is finished, your right to access such information will be reinstated.

What happens to your information, biological samples, images, and/or audio/video recordings that may be collected as part of the study if you do not wish to continue with the study or if you want to withdraw your authorization for their use or disclosure under this HIPAA Authorization?
You may withdraw your permission to use and disclose your health information at any time. You can do this by sending written notice to the study doctor. Your decision to withdraw your Authorization will not involve

any penalty or loss of access to treatment or other benefits to which you are otherwise entitled.

If you withdraw from the study and you do not tell the study team, your contact information may be used by the study team to contact you, your family or your personal doctor, or to search publicly available records to find out how you are doing. These uses of your information may continue until BioNTech/Pfizer determines the study is complete, which may take many years, or until you withdraw your authorization, as described below.

Your authorization for the use and sharing of your personal information under this Authorization does not expire unless you withdraw your authorization.

If the research site is located in California, Delaware, Indiana, or Washington, this authorization will expire on 31Dec2070.

There is no expiration of this authorization except for research conducted in the states listed above.

If you withdraw from the study but do not withdraw your Authorization, your personal information will continue to be used in accordance with this Authorization and applicable law until this study ends.

If you withdraw your authorization:

- You will no longer be able to participate in the study; and
- No new information, biological samples, images, and/or audio/video recordings will be collected about you or from you by the study team unless you have a side effect related to the study.
- Information that has already been gathered may still be used and given to others.

Even if you withdraw your authorization:

- The study team may continue to report any adverse effects or other safety event that you experience due to your participation in the study to BioNTech/Pfizer;
- Your Coded Information will continue to be 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 laws; and
- Any biological samples that have been collected from you will be handled as described in the "Process for Participants who Wish to End Study Participation" section in the main consent document.

Communication via text message

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

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

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

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

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

AUTHORIZATION

By signing below, I authorize my personal information to be used and disclosed as described above. I understand I have a right to receive a copy of this Authorization.

_____

Printed name of participant

_____

Signature of participant Date of signature§

§Participant must personally date their signature.