INFORMED CONSENT FORM AND HIPAA AUTHORIZATION (PHASE 2/3)

TITLE: A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY ADULTS

PROTOCOL NO.: C4591001
IRB Protocol # 20201000

SPONSOR: BioNTech. Pfizer is conducting the study for BioNTech

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

The purpose of this form is to help you decide if you want to be in the research study.

Before you decide if you want to take part in this research study, it is important that you read the information below.

This form may use words you do not understand. Please ask the study doctor or the study staff to explain any words or procedures that you do not clearly understand.

If you sign this form, it means that you agree to take part in this study. This form describes what the study is about and what will happen. It also tells you about the risks and benefits of the study.

After reading this form and talking with the study staff, you should know which parts of the study are medical care and which are experimental. Please ask any questions you have.

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.

If you have questions, concerns, or complaints, or 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 the first page.

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 (888)-303-2224 or (800) 562-4789, irb@cgirb.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 subject.

Brief Summary of this Study

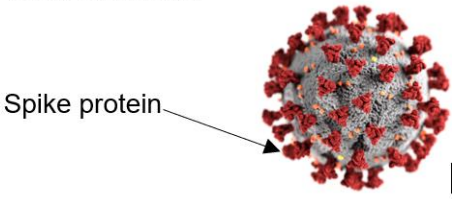
This is a research study involving both Pfizer and BioNTech. Pfizer and BioNTech are separate companies who are cooperating to perform this study. Pfizer is responsible for conducting this study. BioNTech is the regulatory sponsor of this study. Funding for this study is provided by BioNTech and Pfizer and the study doctor/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 quickly started to look for treatments and ways to prevent COVID-19. There are no currently licensed (U.S. Food and Drug Administration [FDA] approved for sale) vaccines for COVID-19.

Vaccines help your body to produce antibodies to help you to fight off a disease. This research study involves 2 investigational vaccines to prevent COVID-19, that will be given to healthy volunteers. “Investigational” means that the study vaccines are currently being tested. They are not approved by the U.S. Food and Drug Administration (FDA). The vaccines are given by injection. The vaccines are slightly different but work in the same way. The study will also test each of these vaccines at different dose levels (amounts of vaccine).

These vaccines do not contain the whole virus, or the parts of the virus that can make you ill, instead the vaccines are made up of part of the virus’s genetic code, surrounded by fatty particles called lipids. They use your own cells’ protein making machinery to produce some, or all, of the spike protein seen on the outside of the virus. This spike protein, made by your 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.

Coronavirus



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 loss of benefits to which you are otherwise entitled 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 penalty or losing any benefits or medical care to which you are otherwise 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.

What is the purpose of this study?
The World Health Organization (WHO) has declared COVID-19 to be a pandemic (a disease that has spread all over the world and is affecting lots of people); finding a vaccine to prevent COVID-19 is an urgent need. To test this investigational vaccine as quickly as possible, this study has been separated into 2 phases. In both the phases we will try to see if the vaccine works to prevent COVID-19, as well as:

- **Phase 1** where we choose which vaccines at which dose levels are safest and make the most antibodies.
- **Phase 2/3** where we look at one vaccine at one dose level in lots of people to collect more information about the safety of the vaccines and the amounts of antibodies they produce.

You are being asked to take part in **Phase 2/3.**

The study will compare the results of the people who receive the study vaccine with those who receive a placebo (a placebo looks like the study vaccines but does not contain any active ingredients). In this study the placebo will be salt-water, also known as normal saline. Everyone in Phase 2/3 of the study will receive 2 injections of either:

- Study vaccine followed by study vaccine
- Placebo followed by placebo

In Phase 2/3 everyone who receives the study vaccine will receive the same vaccine at the same dose, that was chosen based on the results from Phase 1.

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. You will also be required to contact the study doctor if you experience any of the COVID-19 symptoms (explained later in this document).

How long will I participate in this study?
You could be in this study for up to about 26 months. You will need to visit the study site 6 to 7 planned times during the study, and any time after you have experienced COVID-19 symptoms and are feeling better in about a month's time.

How many people will take part in this study?
Approximately 30,000 healthy people could take part in the 2 phases of this study. In Phase 2/3 of the study up to 29,286 people will take part.

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 the study vaccine or placebo. For every 1 person who receives the study vaccine, 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 vaccine or placebo, but the person who gives you the vaccine will know because the vaccine and placebo do not look the same. However, the syringe will be covered with a label so the contents are not visible and the person that 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 whether you have received study vaccine or placebo.

The study vaccine or placebo 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 or placebo, you will be asked to wait at the study site for at least 30 minutes for observation after receiving the study vaccine or placebo.

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.

For people taking part in Phase 2/3, the study doctor or nurse will:

Visit Number	1	2	3	4	5	6
Visit Description	**Study Vaccine 1[a]**	**Study Vaccine 2**	**1-Month Visit**	**6-Month Visit**	**12-Month Visit**	**24-Month Visit**
Ask about Medical history as well as date of birth, sex, race and ethnicity	X					
Ask about medicines you are currently taking	X	X	X	X	X	X
Perform clinical assessment	X					
Measure body temperature	X	X				
Measure height and weight	X					
Urine pregnancy test (if appropriate)	X	X				
Ask about other vaccinations you have had	X	X	X	X		
Check you meet all the study requirements	X	X				
Check contraceptives (if appropriate)	X	X	X			
Collect blood sample to test antibody levels	~25 mL		~25 mL	~25 mL	~25 mL	~25 mL
Take a nasal swab	X	X				
Get the study injection	X	X				
Give you an e-diary or help you download one	X					
Vaccination e-diary completion for 7 days (if you are part of chosen group to report potential side effects following vaccination)	X	X				
COVID-19 illness e-diary completion	X	X	X	X	X	X
Ask how you are feeling generally	X	X	X	X	X	X

a. This visit may be conducted across 2 consecutive days

Blood samples for antibody testing
You will have blood taken 5 times during the planned visits of the study. This will be used to test your antibody levels. About 25 mL of blood (about 5 teaspoons) will be collected from your arm using a needle at these visits.

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.

There are 2 parts to the e-Diary. Everyone will need to complete the COVID-19 illness part of the e-Diary on the device or app on your smartphone. The COVID-19 illness e-Diary will prompt you to record any COVID-19 symptoms (see below) every 7 days or at any time you have COVID-19 symptoms.

If you are part of a subset of participants, you will also be instructed by the study team to complete the vaccination part of 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 vaccination part of the e-Diary.

The vaccination part of 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.

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 the study injection.

<u>If You Get COVID-19 Symptoms</u>
If you get any of the following you must contact the study doctor straight away. 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.**

The study doctor may ask you to have a telephone conversation, video call or to visit the site to talk about how you are feeling and if you have needed any other medical care. They will also ask you to take a nose swab or take one from you to check for the coronavirus (only once during each illness). We will give you separate instructions about how to take a nose swab yourself and how to ship the swab to the laboratory if needed. The result from this swab will be provided to the study doctor once it is available, but this will take some time, and cannot be used to diagnose you with COVID-19. This is why it is important that you contact your usual provider if you think you need medical care.

The study doctor will arrange an extra visit to the study site about a month after you became unwell and you will give another 50 mL (about 10 teaspoons) blood sample to test your antibody levels.

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

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

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.

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 above on the first page of this consent document.

Study Vaccine Risks
Based on studies of these vaccines in 248 people (up until June 22nd 2020), and on risks of vaccinations in general, the following risks and discomforts could be expected.

Reactions at the site of injection:
For example, redness, itching, pain, tenderness, swelling.

Other side effects:
Flu-like symptoms, for example, headache, tiredness, chills, loss of appetite, muscle aches, joint aches, increased body temperature (fever), sweating.

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.

As with any vaccine given by injection, people may have an allergic reaction. The allergic reaction could be minor (rashes) or more severe (swelling of the face or lips and/or shortness of breath). A severe allergic shock (anaphylactic shock) could occur. Very rarely, people may have a nervous system reaction (for example, a seizure) after a vaccine.

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 COVID-19 vaccines, but at the moment we do not know whether the study vaccines could make a later COVID-19 illness more severe. That is one of the reasons why you are asked to contact your study doctor if you develop symptoms that might be caused by COVID-19 (for example, fever, cough, shortness of breath).

Placebo Risks
As the placebo injection contains salt-water and no active ingredients, the chances of having 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.
- **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 for 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 6 months after you 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.

What are possible benefits of this study?
If you receive one of the study vaccines and it is effective for you, your chances of getting COVID-19 may be reduced. It is not known yet whether the study vaccines may reduce the chance of you getting COVID-19, so you may not directly benefit from participating in the study. Information learned from the research study may help other people in the future

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.

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.

What happens if I am injured during this study?
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.

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 result in any penalty, will not affect your regular medical care or any benefits to which you are otherwise 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. If you decide to leave the study early, there may be risks with this decision. You should discuss these risks with your study doctor. You may be asked to return to the clinic for tests.

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.

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 (such as the FDA).

The study team will give you a HIPAA Authorization. It describes what happens to your personal information (including your biological samples) and how it may be used if you withdraw from the study.

What will I have to pay for if I take part in this study?
You will not need to pay for any of the study vaccines (COVID-19 Vaccine or placebo), study-related procedures, or study visits. You or your insurance company will 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.

Will I be paid for taking part in this study?
You will be paid $119 after each completed study visit.

You also will be paid $5.00 for each weekly illness diary completion for the duration of the study.

Some payments and reimbursements will involve using a third-party vendor, working on behalf of BioNTech/Pfizer. This vendor will support the payment and reimbursement process. In order to do this, you will need to provide the vendor with certain personal information about you. 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 payment will be made available to you.

How will my information be protected?
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.

Your records may be reviewed 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/Pfizer business or rights to the product under study;
- Government or regulatory authorities (including the U.S. Food and Drug Administration [FDA] and authorities in other countries); and
- Institutional/Independent Review Board(s) (IRB) or Independent Ethics Committee(s) (IEC) overseeing this study.

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.

The information released about you will not directly identify you (for example, by name, address, or social security number), unless it is required by law. Instead, a code number will be used for your information.

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.

What will happen to my personal information?
The study team will give you a HIPAA Authorization. The HIPAA Authorization 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.

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).

Signatures

Agreement to Participate and to Process Data
1. I confirm I have read or, the consent document has been 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 understand that taking part is voluntary and that I am free to stop taking part in this study or to withdraw my consent at any time. I do not need to give any reason and my regular medical care and legal rights will not be affected.
3. 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.
4. 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.
5. 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.
6. I agree to take part in the study described in this document.

_____
Printed name of participant

_____ _____
Signature of participant Date of signature[§]

§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.

HIPAA AUTHORIZATION

This Authorization 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 loss of benefits to which you are otherwise entitled or change to your regular medical care or payment for that care.

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, medical records, data from this study (including study results from tests any physical exams and procedures), demographics (for example, age and gender) and other sensitive information that is needed for this study such as 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.

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 stored by the study team at your study site. Your medical records that include information that directly identifies you may be uploaded to a secure system so that BioNTech/Pfizer and/or BioNTech/Pfizer representatives can review and verify study data. The record upload 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. The study site 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/Pfizer 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;
- provide you with reimbursement and payments, 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 such as the FDA;
- 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), for example to provide certain updates related to appointment reminders and payment alerts via text message and/or email message (standard text messaging rates will apply if you select this option);
- 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, 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 Authorization and applicable law.

What happens to my personal information that is sent outside the study site?
The study site is required by HIPAA to protect your personal information. After your information is shared with others, such as BioNTech/Pfizer and individuals and groups listed above, it may no longer be protected by this HIPAA. These groups are committed to keeping your health information confidential.

Before the study team transfers (shares) 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 reviewed this study; and
- Government or regulatory authorities (such as the FDA);

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

- **Conducting the study**, including:
    - Examining your response to the study vaccines;

- 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 (such as the FDA);
  - 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), unless a different retention period is required or permitted by law.

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.

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 been reviewed by IRBs, or other similar review groups.

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.

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 study site 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.

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

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

If the research site is located in California, Delaware, Indiana, Washington, or Wisconsin, 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 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 vaccine. This will only be done if allowed by the law.

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 the study ends.

If you decide to withdraw your Authorization:

- 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 unless you have a side effect related to the study;
- 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 and shared by BioNTech/Pfizer to guarantee the integrity of the study, to determine the safety effects of the study vaccines, 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 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.

AUTHORIZATION

By signing this form, I allow the use or disclosure of my health information. I will receive a signed and dated copy of this Authorization.

_____

Printed Name of Participant

_____

Signature of Participant **Date**