Pfizer	**CT05-GSOP-RF04 7.0**	**PHASE 2/3 CLINICAL STUDY INFORMED CONSENT TEMPLATE**	**01-Jul-2019**

Protocol Number: C4591015		**ICD Version Date: 08Jul2021**	
☐ **Study** ☐ **Country** ☒ **Site**	**Language: English**	**Center ID:** 1183	**Country:** United Kingdom
ICD Derived From: Study Main V6_02Jul2021 and country ICD V5_05Jul2021			

PARTICIPANT INFORMATION SHEET AND CONSENT DOCUMENT COVER LETTER

Thank you for taking the time to consider if you and your unborn baby would like to join this study. We understand that this may be a difficult decision. This participant information sheet and 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.

Taking part in this study is **completely voluntary (your choice)**. Take as long as you need to make your decision. Your standard of care will not be affected whatever choice you decide to make. You 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 take part, it may turn out that you do not meet the study's entry requirements.

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

If you choose to take part in this study, **you will be asked to sign the consent document** before you start the study to let the study team know your decision. You can withdraw consent at any time and this will not affect you or your baby's care.

You will receive a signed copy of the consent document for your records. Please keep this participant information sheet and consent document for your reference.
We appreciate you taking the time to consider whether to take part in this study.
Sincerely,

Asma Khalil
Study Doctor

PARTICIPANT INFORMATION SHEET AND CONSENT DOCUMENT TO TAKE PART IN STUDY
Table of Contents

This Table of Contents describes the different sections of this information sheet and consent document. Please read through all sections of this consent document before making your decision about whether or not you would like to be considered to participate in this study.

PARTICIPANT INFORMATION SHEET AND CONSENT DOCUMENT TO TAKE PART IN STUDY

1. Key Study Information and Contact Information

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

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

If you have any general questions about your rights, or your baby's rights, as a study participant, or would like to obtain information from, offer suggestions to, or speak with someone not directly involved in the study, you may contact, Patient Advice and Liaison Services (PALS) listed below.

Name of Study: A Phase 2/3, Placebo-Controlled, Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of a SARS-CoV-2 RNA Vaccine Candidate (BNT162b2) against COVID-19 In Healthy Pregnant Women 18 years of Age and Older

Sponsor Consent Version Number (Study/Country/Site): 6.0 / 5.0 / 5.0

St George's Study Number: C4591015 1183

Sponsor Study Number: C4591015

IRAS Number: 295903

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

Name of Principal Investigator (Study Doctor): Professor Asma Khalil
Professor Paul Heath (Co-Lead)

Study Site Contact Information:

Contact Person: Professor Asma Khalil, Paediatric Infectious Diseases Research Group

Address: St Georges University of London, Vaccine Institute, Room 0.122 Ground floor Jenner Wing, Cranmer Terrace, Tooting, London, SW17 0RE

Phone Number (Normal Business Hours): 020 8725 3887

Phone Number (Off-Hours or Emergency): 07759 536681

Patient Advice and Liaison Services (PALS):

Contact Person: pals@stgeorges.nhs.uk

Address: PALS Office, St George's Hospital, Blackshaw Road, London, SW17 0QT

Phone Number: 020 8725 2453

2. Brief Summary of this Study

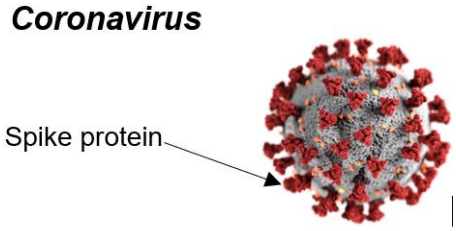
This is a research study involving both Pfizer and BioNTech. Pfizer and BioNTech are separate companies who are cooperating to perform this study. Pfizer is responsible for conducting this study. BioNTech is the regulatory sponsor of this study. Funding for this study is provided by BioNTech and Pfizer and the institution (site) will be paid to conduct this study.

A new respiratory disease appeared in Wuhan, China in December 2019 and has since rapidly spread 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). There are currently no licensed (available for general use) vaccines for COVID-19. The MHRA (Medicines Healthcare Regulatory Authority) has authorised the use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 under an Emergency Use Authorisation (EUA) in individuals 16 years of age and older who have specific risks for developing COVID-19.

Vaccines help your body to produce antibodies to help you to fight off a disease. This research study involves an investigational vaccine, which has received EUA approval for non-pregnant people in the UK to prevent COVID-19, that will be given to healthy women who are 18 years of age or older and expecting a healthy baby. It is normal for immune responses to alter during late pregnancy to avoid a mother's immune system from injuring their baby around the time of birth. However, this makes pregnant women more vulnerable to certain infections and, for this reason, it is standard practice in the UK to vaccinate pregnant women against other viral infections such as flu. Taking part in this study will not affect you receiving your flu jab as per your standard of care.
Unfortunately, a few women have become seriously ill with COVID-19 in late pregnancy. We therefore wish to establish whether vaccinating against COVID-19 is safe for them and their babies and to determine whether it is beneficial if given in later pregnancy. The study doctor will determine whether you and your unborn baby would be suitable for the study. If you decide to join the study and are found to be suitable, you will be given 2 doses of the study injection before your baby is born, which could be either the COVID-19 investigational vaccine or a placebo injection (The placebo injection in this study is safe and is a saline (salt water) solution and does not contain any active ingredients).

After your baby is born, you will be told if you were given the placebo injection or the COVID-19 investigational vaccine while you were pregnant. If you were given the placebo injection you will be given 2 doses of the COVID-19 investigational vaccine after your baby is born. This means that every woman in the study will be given the COVID-19 investigational vaccine either while they are pregnant or shortly after giving birth. It also means that some women will be given 2 injections and some women (in the placebo group) will have 4 injections (2 while pregnant and 2 after the baby is born).

The investigational vaccine is made up of part of the virus's genetic code, surrounded by fatty particles called lipids, it does not contain the whole virus, or the parts of the virus that could make you or your unborn baby ill. The part of the virus' genetic code contained in the investigational vaccine uses 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 from your arm and testing them. We also want to see if these antibodies are transferred to your baby and will take blood samples from your baby after he/she is born.



Up until June 2021, the safety of BNT162b2 (COVID-19 investigational vaccine) 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 authorisation in many countries by the end of April 2021 about 400 million doses have been distributed. Based on the available data, the following side effects have been determined to be caused by BNT162b2 vaccine: Injection site pain, injection site swelling, fatigue (tiredness), increased body temperature (fever), chills, headache, diarrhoea, joint aches, muscle aches, feeling sick (nausea), being sick (vomiting), injection site redness, enlarged lymph glands, allergic reaction (symptoms may include rash, itching, hives, and swelling

of the face or lips), decreased appetite, lethargy, sweating and night sweats, pain in arm, feeling weak or unwell, and severe allergic reaction (anaphylaxis).

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

Taking part in this study is voluntary (your choice). There is no penalty or change to your, or your baby's regular standard care if you decide not to take part. You can choose to take part in the study now, and then change your mind later at any time without losing any benefits or medical care to which you, or your baby, are entitled. We encourage you to have conversations with your family, caregivers, doctors, and study team about taking part in this study and whether it is right for you and your unborn baby. 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 the consent document for your records. Please keep this participant information sheet and consent document for your reference.

3. What is the purpose of this study?

The World Health Organization (WHO) has declared COVID-19 to be a pandemic (a disease that has spread all over the world and is affecting lots of people); finding a vaccine to prevent COVID-19 is an urgent need. Pregnant women might be at increased risk of severe illness from COVID-19 compared to non-pregnant women. There may also be an increased risk of adverse pregnancy outcomes, such as preterm birth,

among pregnant women with COVID-19. This study will investigate whether this vaccine is safe for pregnant women and their unborn babies and record the amounts of antibodies they produce in response to the vaccine. We will also see if the investigational vaccine works to prevent COVID-19 in women given the vaccine whilst pregnant. After your baby is born you will be told if you were given the placebo injection or the investigational COVID-19 vaccine whilst you were pregnant. Every woman in the study will be given the COVID-19 investigational vaccine either whilst they are pregnant or shortly after giving birth.

4. How long will my baby and I be in the study?

The length of time you are in the study will depend on whether you are given the investigational COVID-19 vaccine whilst pregnant or shortly after your baby is born. You will be in the study for about 7-10 months but the duration will depend on when your baby is born and whether you received placebo injection or the COVID-19 investigational vaccine at the beginning of the study.

Your baby will be in the study for up to approximately 6 months. Your baby will have a clinic visit at the study site when he/she is about 6 months old.

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

There will be about approximately 700 healthy pregnant women and their unborn baby taking part in this study. There will be approximately 62 women taking part in the United Kingdom.

If enrollment ends before you are given the first study vaccine, it is possible that you/your baby may not be allowed to join the study.

6. What will happen during this study?

All women who take part will need to visit the study site for 4 planned visits before their baby is born and then 2 more visits after the baby is born. Visits that occur before delivery of your baby include:

1. screening and your **first study injection visit** (these could take place on the same day),
2. your **second study injection visit**, which is about 3 weeks after the first injection,

3. **2-week follow-up** visit,
4. **1-month follow-up** visit,

A study visit should occur on the day your baby is born, or shortly after for blood sampling and recording some information (see tables below).
After your baby is born you will have:

- A phone call about a week after your baby is born to see how you and your baby are,
- A clinic visit about 1-month after you have given birth. At this visit you will be told if you were given the placebo injection whilst you were pregnant or the investigational COVID-19 vaccine.

If you were given the investigational COVID-19 vaccine whilst you were pregnant you will only need to come back to the clinic for 1 more planned visit. This will be when your baby is around 6 months old.

If you were given the placebo injection whilst you were pregnant you will be given your first investigational COVID-19 vaccine injection about 1 month after your baby is born. You will need to come back to the clinic about 3 weeks later to receive your second investigational COVID-19 vaccine injection. You will have a follow-up telephone call about 1 month after your second vaccination. This follow-up call will be the end of the study for you. Your baby will continue to be followed up until they are 6 months old.

- Every baby will need to have a clinic visit when they are about 6 months old.

The study team will tell you when you and your baby need to come for your visits. Extra visits or contacts may also be necessary if you, or your baby develop any signs or symptoms of COVID-19 illness during the study, or if you have any severe symptoms after your vaccinations that you are given whilst you are pregnant.

Before any study procedures begin, you will be asked to read and sign this participant information sheet and consent document.

After signing this consent document, the study doctor will check if you, and your unborn baby, meet all the requirements to take part in this study. If you, or your baby, 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 – When you are pregnant

Once the study doctor has confirmed you, and your unborn baby, meet the study requirements, you will be randomly assigned (you will be allocated by a computer system to a treatment group for the study. This is called randomisation and the research team do not influence this) to receive the investigational COVID-19 vaccine (BNT162b2 30 micrograms) or placebo injection. The placebo injection contains salt-water and no active ingredients. For every 1 pregnant person who receives the investigational COVID-19 vaccine, 1 other pregnant person will receive the placebo injection. No one (including you, your personal doctor or the study team) can choose this assignment.

This part of the study is an 'observer-blind study', which means that you and the study doctor **will <u>not</u> know** whether you are receiving the investigational COVID-19 vaccine or placebo injection while you are pregnant. The person who gives you the injection will know which you are getting because the investigational COVID-19 vaccine and placebo injection 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 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 investigational vaccine or placebo injection.

The investigational COVID-19 vaccine or placebo injection 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 injection, you will be asked to wait at the study site for at least 30 minutes for observation after receiving the injection.

Study Vaccines – After your baby is born

When you come for your visit about 1-month **after** your baby is born you will be told if you were given the investigational COVID-19 vaccine (BNT162b2 30 micrograms) or placebo injection whilst you were pregnant.

If you were given the investigational COVID-19 vaccine whilst you are pregnant you will not need any further injections in the study.

If you were given the placebo injection while you were pregnant you will be given your first dose of investigational COVID-19 vaccine as an injection into the muscle in your upper arm at this visit. You will be given your second injection of investigational COVID-19 vaccine about 3 weeks later. In this part of the study, you and your study doctor **will know** that you are getting the investigational COVID-19 vaccine.

PARTICIPANT INFORMATION SHEET AND CONSENT DOCUMENT TO TAKE PART IN STUDY

Overview of Study Procedures and Assessments

The tables below show the tests and procedures or assessments that you and your baby 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 or if you or your baby have any COVID-19 like symptoms.

If you were given the COVID-19 investigational vaccine whilst pregnant you will need to attend a follow-up visit about 6 months after delivery in order to give a blood sample and provide information about your health, including HIV status (if applicable)

PARTICIPANT INFORMATION SHEET AND CONSENT DOCUMENT TO TAKE PART IN STUDY

Summary of Planned Study Visits and Procedures for EVERY Woman Taking Part

	Before your baby is born					After your baby is born	
Visit Description and Visit Timing	**Study Vaccine 1**	**Study Vaccine 2**	**2-Week Visit**	**1-Month Visit**	**Delivery**	**1-Week After Delivery (phone call)**	**1-Month After Delivery**
Review participant information sheet and sign consent document	✓						
Questions about your health	✓	✓	✓	✓	✓	✓	✓
Questions if you smoke or drink alcohol	✓						
Phase 3 only: For participants who are HIV-positive, record latest CD4 count and HIV viral load	✓		✓	✓	✓		✓
Blood samples for antibody testing (~20 mL per blood sample)	✓ before the study injection	✓ Only if you are one of the first 200 women to take part	✓	✓	✓		
Measure your height, weight and do an ultrasound (if applicable)	✓						
Physical and Obstetric examination (external only)	✓	✓		✓			
Study injection	✓	✓					
E-diary training, and give you an e-diary or help you download one	✓						
Vaccination e-diary completion for 7 days after each vaccination	✓	✓					
COVID-19 illness e-diary completion	✓	✓	✓	✓	✓	✓	✓
Discuss any vaccinations, medications or treatments you may be taking	✓	✓	✓	✓	✓	✓	✓
Tell you which vaccine you had							✓

PARTICIPANT INFORMATION SHEET AND CONSENT DOCUMENT TO TAKE PART IN STUDY

	Before your baby is born					After your baby is born	
Visit Description and Visit Timing	**Study Vaccine 1**	**Study Vaccine 2**	**2-Week Visit**	**1-Month Visit**	**Delivery**	**1-Week After Delivery (phone call)**	**1-Month After Delivery**

NOTE:

If you were given the COVID-19 investigational vaccine while pregnant you will need to attend a follow-up visit about 6 months after delivery to give a blood sample and provide information about your health, including HIV status (if applicable) You will still need to fill out the illness diary.

PARTICIPANT INFORMATION SHEET AND CONSENT DOCUMENT TO TAKE PART IN STUDY

Summary of Additional Planned Study Visits and Procedures for Women who had placebo injection while pregnant

Visit Description and Visit Timing	First COVID-19 injection visit About 1 month after baby was born	Second COVID-19 injection visit About 3 weeks after the first COVID-19 injection visit	1-Month follow up Phone call About 1 month after the second COVID-19 injection visit
Tell you that you had placebo injection while pregnant	✓		
Questions about your health	✓	✓	✓
Phase 3 only: For participants who are HIV-positive, record latest CD4 count and HIV viral load			✓
Take a swab from your nose	✓	✓	
Blood samples for antibody testing (~20 mL per blood sample)	✓		
Make sure you are ok to have the investigational COVID-19 injection	✓	✓	
Investigational COVID-19 injection	✓	✓	
Discuss any vaccinations, medications or treatments you may be taking	✓	✓	✓

PARTICIPANT INFORMATION SHEET AND CONSENT DOCUMENT TO TAKE PART IN STUDY

Summary of Planned Study Visits and Procedures for Your Baby

	Birth	1-Week Follow-up Phone call	6-Month Follow-up
Questions about your baby's health	✓	✓	✓
Collect information about feeding your baby		✓	✓
Cord blood collection for antibody assessment, or blood sample from baby if cord sample not available	✓		
Blood Sample (~5ml or 1 teaspoon of blood)			✓
Temperature, heart rate, oxygen saturation level and respiratory rate	✓		
Physical examination	✓		
Discuss any medications, treatments, or vaccinations	✓	✓	✓

Please note that if your baby's visit 1 assessments are not all completed on the day of your baby's birth, they should be done within 7 days.

Your blood samples for antibody testing

You will have to give a blood sample at most clinic visits. It is expected that most women will have to give between 5 or 6 blood samples. You will also need to give an extra blood sample each time if you become ill with COVID-19 like symptoms.

Each blood sample will be about 20mL (about 4 teaspoons) and will be collected from your arm using a needle.

Your blood samples will be used to test if you already had antibodies against the coronavirus that causes COVID-19 when you enrolled in the study and may be used to test your antibody levels after vaccination, or after a COVID-19 like illness.

Your Baby's Blood samples for antibody testing

The study team will collect about 10mL of blood (about 2 teaspoons) blood sample from your baby's cord when removed after delivery which would be painless. If the study team are not able to collect a blood sample from your baby's cord at the time of delivery it is possible that your baby may have to give a blood sample that will be collected either from a finger/heel prick or from a vein through a needle . If this happens the study team will weigh your baby and work out the amount of blood that they will collect. For a 3kg (7lb) baby a 2ml (half teaspoon) blood sample would be collected.

Your baby will have blood taken when they are 6 months old. This will be used to test if your baby has antibodies against the coronavirus that causes COVID-19. About 5mL of blood (about 1 teaspoon) will be collected from your baby either from a finger/heel prick or from a vein through a needle.

Your baby may also need to give an extra blood sample each time he/she becomes ill with COVID-19 like symptoms. The study team will weigh your baby and work out the amount of blood that they will collect. Each blood sample will be collected using a needle and will be up to 5mL (up to about 1 teaspoon) depending on how much your baby weighs.

E-Diary

At Visit 1, the study team will explain what you need to do and 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.

The e-Diary includes a **COVID-19 illness part** and a **vaccination part**.

You will need to complete the COVID-19 illness e-Diary once a week for the whole time you are in the study to say if you have any COVID-19 symptoms or not. You will also need to fill out the COVID-19 illness e-Diary if you have COVID-19 symptoms (the symptoms are listed in a later section of this document). Once your baby is born you will also need to say if your baby has any COVID-19 symptoms or not.

You may receive text messages to the device or your own smartphone, or emails (if you provide your email address) to remind you to complete the COVID-19 illness part of the e-Diary.

You will also need to complete the vaccination part of the e-Diary every evening for 7 days after both injections that you are given when you are pregnant. You will start on the evening of your injection and then complete the diary for 6 more days (7 days in total).

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 that you may have after your injection. If you have any severe symptoms after your injection, any redness or swelling that is bigger than 20 units on the measuring device (bigger than 10 cm), or a temperature of 39.0°C or higher you must contact your study doctor and the study doctor or nurse may schedule an extra visit. It is very important that you complete the e-Diary every evening as instructed. If you do not, your study doctor or nurse may contact you to check how you are.

If You Get COVID-19 Symptoms

If you get any of the following, at any time while you are in the study, 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;**
- **Diarrhoea;**
- **Vomiting.**

If you have any of these symptoms the study team will ask you to have a telephone conversation, video call or have an in-person visit to talk about how you are feeling and if you have needed any other medical care.

If you have an in-person visit the site staff will take a swab from your nose, if you have a telephone or video call you will need to take a swab from your nose. The swab is to check for the coronavirus, you will be told how to do this.

The study doctor will arrange an extra visit to the study site about a month after you became unwell and you will need to give a 20 mL (about 4 teaspoons) blood sample to test your antibody levels.

We will give you separate instructions about how to take a nose swab and how to send 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 if you have COVID-19. This is why it is important that you contact your usual provider (GP) if you have COVID-19 symptoms and think you need medical care.

If you are diagnosed with COVID-19, for the purposes of the study, the study doctor will contact your usual provider (GP), and any facility where you are treated, to obtain details and collect medical records: **by signing the consent document, you agree to this**.

What happens if I have a positive nose swab test result?

Nose swabs at Visits 1 and 2, and at the time of a possible COVID-19 illness will be tested in a research laboratory.

Results from the Visit 1 and 2 swabs, and all results from the illness visit swabs, will be provided to your study doctor. This will take some time so you should not rely on these results for medical treatment.

If you have any potential COVID-19 symptoms with a positive nose swab test result before Visit 2 you will be given the second study injection as planned. At the visit 1 month after you give birth the study team will tell you if you had the placebo injection or the COVID-19 investigational vaccine. If you were given the placebo injection and had a positive nose swab test between Visit 1 and Visit 2 you WILL still be allowed to have the COVID-19 injection.

If you have positive nose swab test before Visit 2 but no potential COVID-19 related symptoms, you will be given the second study injection as planned.

Important note: positive test information will be sent to the NHS track and trace and they will contact you for further discussion.

If Your Baby Gets COVID-19 Symptoms

The site staff will give you a list of symptoms and if your baby gets anything on that list at any time while your baby is in the study, you must contact the study doctor straight away.

Note that this is not instead of your baby's routine medical care. Please contact your usual provider (GP), as well as the study doctor if you think your baby needs medical care.

If your baby has one or more of the symptoms the study team will ask you to have a telephone conversation, video call or have an in-person visit to talk about your baby and see if he/she has needed any other medical care.

If your baby has an in-person visit the site staff will take a swab from baby's nose, if you have a telephone or video call you will need to take a swab from your baby's nose (you will be told how to do this). The swab is to check for the coronavirus.

The study doctor will arrange an extra visit to the study site about a month after your baby became unwell and your baby will need to give a blood sample to test their

antibody levels. The exact amount of blood will depend on how much your baby weighs, but it would not be more than 5mL (1 teaspoon full).

We will give you instructions about how to send the swab to the laboratory if needed. The result from this swab will be provided to the study doctor once available, but this will take some time, and cannot be used to diagnose if your baby had COVID-19. This is why it is important that you contact your usual provider (GP) if your baby has COVID-19 symptoms and think he/she may need medical care.

Leaving the Study Early

Taking part in this study is completely voluntary. You, or your baby, may withdraw from the study at any time at your own request, or you/your baby may be withdrawn at any time at the discretion of the investigator for safety, behavioral, compliance, or administrative reasons. You do not need to give a reason for leaving the study.

After the study

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

However, since the vaccine has been granted emergency use authorisation for non-pregnant adults, you may be able to receive it as part of standard care.

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

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

- You don't understand anything about the study
- You are not able to comply with the study requirements
- There are changes in your or your baby's health
- Your e-diary device or APP is not working properly
- You or your baby 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 or your baby have any COVID-19 symptoms, even if they are mild
- Call the study doctor or study staff if you have a large reaction (redness/swelling) at the injection site, or any severe reaction or temperature of 39°C or higher after the injection you are given whilst you are pregnant
- 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 as taking part in more than one study at the same time could put you or your baby's safety at risk
- Take part in the study only at this location. Participating in this study more than once at different locations could put your/your baby's safety at risk
- Tell other doctors, nurses, and health care providers about your/your baby's participation in this study by showing the information card provided to you by the study team.

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

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

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 in Section 1 of this participant information sheet and consent document.

Study Vaccine Risks

Up until June 2021, the safety of BNT162b2 (COVID-19 investigational vaccine) has been studied in the clinical trials that have included about 28,500 who have received at least one dose of the vaccine. In addition, since the vaccine has been approved for emergency use in or received a conditional marketing authorisation many countries, by the end of April 2021 about 400 million doses have been distributed. As this is an

investigational vaccine the study team do not know all the effects the vaccine will have on you, or your unborn baby, however thousands of pregnant women globally have now received the investigational vaccine outside of clinical trials and there have been no safety concerns reported to date.. 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, diarrhoea, 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 and swelling of the face or lips), 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.

Not known how common: 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. 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 investigational 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.

The study vaccine itself 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).

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 injection, some people who received the placebo injection reported pain, bruising, swelling and redness at the site of injection.

Risks from Study Procedures

Risks and possible discomforts you, or your baby, 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.

What will happen to our blood and nose swab samples?

Your, and your baby's blood and nose swab samples will be used only for this research, after which they will be destroyed. Each sample will be labelled with a code so that the laboratory workers testing the samples will not know who you or your baby 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, or your baby's, DNA will be performed. You may request that your, or your baby's, samples, if they can be identified, be destroyed at any time. Any data already collected from those samples will still be used for the study.

9. What are possible benefits of this study?

Vaccination with this investigational vaccine has been shown to be effective in preventing COVID-19 in the groups of people already studied, but not yet in pregnant women. Because of this, and the fact that you may receive the placebo injection, you still need to follow local recommendations about how to avoid COVID-19 (for example, social distancing and mask use).

10. What other choices do I have if my baby and I do not join this study?

This study is for research purposes only. Your alternative is to not take part in this study. You may choose to accept a vaccine via standard care as and when one is available for pregnant women.

11. What happens if my baby and I are injured during this study?

If you or your baby experience a research injury, emergency medical treatment will be provided at no cost to you. A research injury is any physical injury, illness or disability caused by:

1. administration of the study medicine; or

2. any study procedure that would not have occurred but for your/your baby's inclusion in the study.

Compensation may be available for such research injuries, depending on a number of factors including the seriousness of the disease, the likelihood of adverse reactions, any warnings given, the risks and benefit of established treatments relative to these of the study medicines and compliance with study directions. Your study doctor will advise you about these factors.

In assessing claims for compensation regarding any injury caused by taking part in this study, BioNTech and Pfizer follow the terms of the guidelines of the Association of the British Pharmaceutical Industry ("ABPI") a copy of which is available on request. The complaints procedure of the hospital where the trial is being conducted is also available.

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

Whilst you are taking part, the study team will tell you in a timely manner if new information is learned during the study that could change your mind about continuing in this study. If you decide to withdraw from the study, or if you decide that you will withdraw your baby 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 for yourself/your baby to continue with the study, information about your and your baby's health will continue to be collected as described in Section 6.

If you decide that you, or your baby, will stop participating in this study, you must notify the study doctor.

Sometimes the study doctor or BioNTech/Pfizer may decide to take you, or your baby, 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, or your baby's, best interest or that you/your baby are no longer eligible to participate; or
- The study is stopped by BioNTech/Pfizer, the independent ethics committee (IEC) (a group of people who review the study to protect your rights), or by a government or regulatory agency.

You may request that any samples that have been collected from you or your baby as part of the study be destroyed, and in some countries, local laws or regulations may require that your/your baby's samples be destroyed regardless of whether you specifically make such a request. However, we cannot guarantee the destruction of

samples because, for example, the sample may no longer be traceable to you/your baby or the samples may have been used up.

13. What will I have to pay for taking part in this study?

You, or your baby will not need to pay for any of the study vaccines (investigational COVID-19 Vaccine or placebo injection), study-related procedures, or study visits.

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

You will not receive any payment for taking part in this study. However, for each visit you/ your baby 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.

If applicable and if you agree to receive reimbursement through an optional Greenphire program (Greenphire is a company working on behalf of Pfizer to support this reimbursement process) that will be proposed to you by the site team, then Greenphire will need to process certain personal data about you. This information will be collected from you by the site staff from the COVID-19 vaccine/C4591015 study and given to Greenphire. In addition, if you choose to not provide the required personal data, Pfizer will make a different method of payment available.

In the event that you decide to withdraw consent, Greenphire will assist Site staff with your request. To do so, you must contact Site staff directly as Greenphire is processing the data on their instructions as the data controller per the General Data Protection Regulation (EU) 2016/679 (“GDPR”).

Greenphire will collect and use your personal data for the following purpose(s):

ClinCard

To issue you a Greenphire ClinCard, which is a debit card that your reimbursable funds are loaded onto when a visit is completed. The funds will be available within 1 business day. In order to assign a ClinCard to you and load funds onto the ClinCard Greenphire will need your Patient ID, Name, Address, and Date of Birth. Greenphire will retain transactional ClinCard data for at least 7 years from study close out, if there is no balance available on the card and you are not associated with any active cards.

Email and/or Text Messaging

You will have the option to receive updates related to appointment reminders and payment alerts via text message and/or email message. Standard text messaging rates will apply. In order to send you messages Greenphire will need your: Mobile Phone Number and/or E-mail Address.

All information is transferred by the site staff to Greenphire in the United States or accessed from the United States in order to process your study-related expenses, including travel expenses and meals, if applicable. If you choose to provide your informed consent, you will allow the transfer of your information to Greenphire for processing. Standard Contractual Clauses in the Data Privacy Agreement (DPA) between Greenphire and the data exporter Pfizer bind both parties to protect your information during transport.

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

15. Will the confidentiality of mine and my baby's medical records be maintained?

Medical records collected during this study will be stored by the study team at your study site and reviewed to verify that clinical trial procedures and/or data are correct.

You/Your baby's medical records may be accessed by:

- Your study doctor and other study team members;
- BioNTech/Pfizer and their representatives (including their affiliated companies);
- People, or organisations providing services for, or collaborating with, BioNTech/Pfizer;
- Any organisation that obtains all or part of the Sponsor's business or rights to the product under study;
- Government or regulatory authorities (including the United States Food and Drug Administration and authorities located in other countries);

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

Under very limited circumstances and if you agree, information that identifies you directly 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
- provide you with transportation and similar support to enable your participation in the study
- provide you with the option to have certain study visits and procedures conducted by home health care professional at your home
- deliver drug to your home **or** pick up specimens/samples
- follow-up on your health status, including using available records (e.g. public databases or the internet) should the study team be unable to contact you using information held on file

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

Your/your baby's personal information will be collected, used, and shared (called "processing") in compliance with applicable privacy laws. You will also be provided a separate Privacy Supplement that describes how your information will be processed and your privacy rights.

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 the 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. Pfizer is the controller of the information uploaded to this electronic system. 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.

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

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

In addition, a plain English summary of the study results will be made available in the EU database at **https://www.clinicaltrialsregister.eu** website. This information will be provided no matter what the study's outcome. To the extent possible, you will be able to access these summaries in the EU database soon after they become available using the following EU trial number for the study: 2020-005444-35.

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 parts 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 or your baby. 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).

17. Consent Form

Study Title: A Phase 2/3, Placebo-Controlled, Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of a SARS-CoV-2 RNA Vaccine Candidate (BNT162b2) against COVID-19 In Healthy Pregnant Women 18 years of Age and Older

Protocol Number: C4591015

IRAS Project ID: 295903

Patient No:

The patient should complete the following:

Agreement to Participate and to Process Data **1.1.1. MATERNAL AND INFANT PARTICIPANTS**	Participant Initials
1. I confirm I have read this Participant Information Sheet and Consent form UK V6 dated 08Jul2021 (or, if I cannot read, a study team	

PARTICIPANT INFORMATION SHEET AND CONSENT DOCUMENT TO TAKE PART IN STUDY

member has read it to me). I understand this information sheet for the study described above and have had the opportunity to ask questions. I have had enough time to review this information sheet. I also have had an opportunity to ask about the details of the study and to decide whether or not to participate.	
2. I also acknowledge that I have received a copy of the Privacy Supplement.	
3. I understand that taking part is voluntary and that I, or my baby, am free to stop taking part in this study at any time. I do not need to give any reason and my/my baby's regular medical care and legal rights will not be affected.	
4. I agree to the study team accessing my/my baby's medical history, including information from medical records and test results and any medical treatment I/my baby receive during the course of the study, and if necessary, contacting my/my baby's doctor or any other health care providers treating me/my baby for access to such information.	
5. I understand that the Sponsor and/or others working with or on behalf of the Sponsor, and regulatory agencies may need access to personal information about me/my baby generated at the study site or collected by the study team for the study. I agree that they may have access to my/my baby's personal information.	
6. I do not give up any of my/my baby's legal rights by signing this consent form. I have been told that I will receive a signed and dated copy of this document.	
7. I agree to my GP being informed of my participation in this study.	
8. I agree that my baby and I will take part in the study described in this document.	
9. OPTIONAL: I agree to use Greenphire for patient reimbursements.	
10. OPTIONAL: I agree to storage of my/my baby's samples for future research.	
11. I understand that in order to take part in this study it is necessary for	

my information to be transferred outside of the UK and EEA, where the protection arrangements may not be to the same standard.	

_____
Printed name of participant

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

§Participant must personally date their signature.

Person Obtaining Consent:

_____
Printed Name of the Person Conducting the
Consent Discussion

_____ _____
Signature of the Person Conducting the Date of signature

Consent Discussion †

†The investigator, or an appropriately qualified and trained person designated by the investigator to conduct the consent process, must sign and date the consent document during the same discussion when the participant signs the consent document.

PARTICIPANT INFORMATION SHEET AND CONSENT DOCUMENT TO TAKE PART IN STUDY

Pfizer Privacy Notice for UK 11.13.18 (13Nov18)

This Privacy Supplement describes how BioNTech/Pfizer will collect, use, and share you/ your baby's information (called "processing") based upon its legitimate interests in guaranteeing the integrity of the study and ensuring high standards of quality and safety of its products to advance public health and scientific research. It also describes you/your baby's privacy rights.

A. What information may be collected about you/your baby during this study?

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

- **Personal information that directly identifies you/your baby** such as your names, address, telephone number, and date of birth.
- **Demographics** such as age and gender.
- **Sensitive personal information** such as your/your baby medical history, data from this study (including study results from tests and procedures) and other sensitive information that is needed for this study such as, HIV/AIDS, substance use disorders, 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).
- **Data from testing and analysis of biological samples** (such as blood or urine)**.** 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. 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.

The records containing your/your baby's information may be accessed by:

- Your study doctor and other study team members;
- BioNTech/Pfizer and their representatives (including their affiliated companies);
- People, or organisations providing services for, or collaborating with, BioNTech/Pfizer;
- Any organisation that obtains all or part of the Sponsor's business or rights to the product under study;

- Government or regulatory authorities (including the United States Food and Drug Administration and authorities located in other countries)

The individuals and groups listed above will use your/your baby's information to conduct this study, ensure the study is conducted correctly and that the study data are accurate, and to comply with legal or regulatory requirements. Your information may also be used to protect your/ your baby's vital interests (for example, a critical medical situation, such as providing information to an emergency department of a hospital where you are being treated).
The study site will retain your/your baby's information for the period necessary to fulfil the purposes outlined above and in the consent document(s), which could be up to 25 years after the end of the study.

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

B. What happens to my/my baby's information that is sent outside the study site?

As described in detail in the consent document, your/your baby's name is replaced with a unique code ("Coded Information") before it leaves the study site. Under very limited circumstances, information that identifies you/your baby directly may be sent to people and/or organisations contracted by BioNTech/Pfizer, in order to provide study logistics, support and care. Your Coded Information may be used by the following:

- BioNTech/Pfizer and their representatives (including their affiliated companies);
- People and/or organisations providing services to or collaborating with BioNTech/Pfizer;
- Any organisation that obtains all or part of the Sponsor's business or the rights to the product under study;
- Government or regulatory authorities, including the United States Food and Drug Administration and authorities located in other countries

The above parties may use your Coded Information to:

- **Conduct the study**, including:
  - Examining your response to the study vaccine;

- Understanding the study and the study results and learning more about COVID-19; and
- Assessing the safety and efficacy of the study vaccine.

- **Comply with legal and regulatory duties** such as:
  - Ensuring the study is conducted according to good clinical practice;
  - Making required disclosures to IRB(s), IEC(s), or government or regulatory authorities;
  - Seeking approval from government or regulatory authorities to market study vaccine (it is possible that these government or regulatory authorities may disclose your Coded Information to other researchers for the conduct of future scientific research); and
- **Publish 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. In some cases genetic and other information from the study that does not directly identify you may be made available to other researchers for further research projects.
- **Improve the quality, design and safety** of this study and other research studies, including developing diagnostic products and tools.

BioNTech/Pfizer will retain your Coded Information for the period necessary to fulfil the purposes outlined above and in the consent document(s), at least 25 years after the end of the study.

Your/your baby's information will be treated in compliance with applicable data protection laws. BioNTech/Pfizer is the controller for any information collected about you/your baby by the site for purposes of conducting the study, and is also the controller of your Coded Information once it leaves the site. Some of the people using your Coded Information may be based in countries other than your country of residence, including the United States. Data privacy laws may be different in these countries. The European Commission has found that some of these countries provide an adequate level of data protection (the full list of these countries is available at this website **https://ec.europa.eu/info/law/law-topic/data-protection/data-transfers-outside-eu/adequacy-protection-personal-data-non-eu-countries_en**).

If your/your baby's information is transferred by BioNTech/Pfizer from the European Union ("**EU**"), European Economic Area ("**EEA**"), and/or Switzerland to other countries

that have not yet been found by European regulators to meet requirements for protection of personal information, BioNTech/Pfizer has in place standard EU data transfer agreements to protect your/your baby's information. Please contact your study team in the first instance if you would like to obtain a copy of these standard data transfer agreements.

C. How are my/my baby's biological samples and images handled?

Data from biological samples or images of you/your baby collected during the study will be handled in the same way as your Coded Information. All samples will be treated as required by law.

D. Can my/my baby's personal information be used for other research?

BioNTech/Pfizer has a legitimate interest in using your/ your baby's Coded Information in the future to support and advance scientific research, including research supporting public health aims. At this time, we do not know the specific details of these 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 optimise access to medicines.
- **Specific safeguards** will be used to protect your/your baby's 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/your baby's Coded Information.
- Using security measures to avoid data alteration, loss and unauthorised access.
- Anonymizing the data by removing and/or replacing information from the Coded Information and/or destroying the link to the Coded Information.
- Assessing data protection systems to identify and mitigate privacy risks, if any, associated to each additional scientific research purpose.
- When required by applicable law, ensuring that the scientific research has the approval of IECs, IRBs, or other similar review groups.

E. What are my data protection rights?

You have the right to request to access, change, move, delete, or object to the use of your/your baby's information. These rights may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate or to comply with our legal duties.

If you wish to exercise any of these rights or have concerns about how your personal/your baby's information is being handled, it is best to contact the Institution (please see the **contact information at Section 1** of the consent document) and not BioNTech/Pfizer. Generally, BioNTech/Pfizer will not know who you are (by name). However, you may find contact details for BioNTech's/Pfizer's data protection officer at DPO.Pfizer.com.

You also have the right to file a complaint with a data protection authority in the United Kingdom: **https://ico.org.uk/make-a-complaint/** or any Data Protection Authority: **http://ec.europa.eu/justice/data-protection/article-29/structure/data-protection-authorities/index_en.htm**.

F. What happens to my/my baby's information if I do not wish to continue with the study?

As noted in the main consent document, you are free to stop taking part in this study at any time. BioNTech/Pfizer, may continue to use your/your baby's Coded Information even if you/your baby stop taking part in some or all of the study activities as necessary for BioNTech/Pfizer to (a) comply with its legal and regulatory obligations and (b) for

PARTICIPANT INFORMATION SHEET AND CONSENT DOCUMENT TO TAKE PART IN STUDY

BioNTech's/Pfizer's legitimate interests in guaranteeing the integrity of the study and ensuring high standards of quality and safety of our products to advance public health and scientific research.

No new information or samples will be collected about you/your baby or from you/your baby by the study team, unless you have told the study team that you agree to provide new information or samples. Even if you do not agree to the collection of new information or samples, the study team may still need to report any adverse event or other safety event that you/your baby may have experienced due to your participation in the study to BioNTech/Pfizer.

In the event BioNTech/Pfizer has already removed all information that could reasonably be used to identify you/your baby, it may continue to use all resulting anonymised data for any purpose, including commercial purposes, and for future scientific research as described in Section D of this Privacy Supplement, as permitted by applicable law.