	CLINICAL STUDY INFORMED CONSENT ADDENDUM	Page: 1 of 9
Protocol Number: C4591001	**Associated ICD Version Date**: Phase 2/3, Adult ICD (02Jul2021)	**ICD Addendum Version Date**: Third Dose of BNT162b2 (08Sep2021)

INFORMED CONSENT/ASSENT ADDENDUM

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 INDIVIDUALS

PROTOCOL NO.: C4591001
IRB Protocol #20201000

SPONSOR: BioNTech. Pfizer is conducting the study for BioNTech

INVESTIGATOR: Donald Martin Poretz, MD
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United States

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

All information in the Main Informed Consent Form and HIPAA Authorization and/or Assent Form still applies.

In this informed consent addendum, “you” always refers to the study participant. If you are a parent/legal guardian, please remember that “you” refers to the study participant. This addendum is also used for participants who cannot consent for themselves to provide assent.

You have already signed a consent form to participate in the research study mentioned above. You are being provided with this addendum because you were enrolled in the study and originally received 2 doses of BNT162b1, BNT162b2 or BNT162b2$_{SA}$ COVID-19 vaccine.

	CLINICAL STUDY INFORMED CONSENT ADDENDUM	Page: 2 of 9
Protocol Number: C4591001	**Associated ICD Version Date**: Phase 2/3, Adult ICD (02Jul2021)	**ICD Addendum Version Date**: Third Dose of BNT162b2 (08Sep2021)

This addendum is part of the consent procedure. It has been written to provide you with additional information on a third dose of BNT162b2. This addendum contains information on a new schedule of study visits and study procedures. It also provides the latest information on BNT162b2 vaccine risks that you will want to know.

Please note you do not need to sign and date this consent addendum to remain part of the main study. If you agree to participate in this part of the study and then change your mind for any reason, you are free to stop participating at any time. All other information in the main consent form that you already signed, which is not addressed in this addendum still applies.

Administering a Booster Dose with BNT162b2 Vaccine

You originally received 2 doses of the investigational vaccine (BNT162b1, BNT162b2 or BNT162b2$_{SA}$) as part of your participation in this study. Some regulatory agencies are now recommending a third dose of BNT162b2 to further enhance immune protection against COVID-19 disease for those who already received two doses of BNT162b2 vaccine. In light of this, you are now being asked by the study site whether you would like to receive a third dose as part of the study and to read, sign and date this consent addendum before starting any new set of study-related procedures.

After signing and dating this consent addendum, the study doctor will check if you meet all of the requirements, and once confirmed you meet all the study requirements, you will receive the third vaccine dose as an injection. This will be given into the muscle in your upper arm in the same way as the first 2 doses and you will be asked to wait at the study site for at least 30 minutes for observation after receiving the vaccine injection.

Overview of Study Procedures and Assessments:

The table below lists the tests and procedures or assessments that you will have done for the remaining duration of the 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.

You will have blood taken 2 times during the remaining planned visits of the study. This will be used to test your antibody levels. About 20mL of blood will be collected from a vein in your arm using a needle at each of these visits.

	CLINICAL STUDY INFORMED CONSENT ADDENDUM	Page: 3 of 9
Protocol Number: C4591001	**Associated ICD Version Date**: Phase 2/3, Adult ICD (02Jul2021)	**ICD Addendum Version Date**: Third Dose of BNT162b2 (08Sep2021)

For participants receiving the third dose of BNT162b2, the study doctor or nurse will:

Visit Number	501	502	503	504
Visit Description	**Vax-3**	**1-Month Follow-up Call**	**6-Month Follow-up Call**	**12-Month Follow-up Visit**
Obtain urine pregnancy test (if appropriate)	X			
Check contraceptives (if appropriate)	X			
Ask about medicines you are currently taking	X	X	X	X
Ask about other vaccinations you have had	X	X	X	
Record latest CD4 count and HIV viral load (for HIV positive participants only)	X	X	X	X
Check you meet all the study requirements	X			
Collect a blood sample to test antibody levels	~20 mL			~20 mL
Take a nasal swab	X			
Give you the study injection, followed by 30 minutes observation period	X			
Contact you by telephone		X	X	
COVID-19 illness e-Diary completion	X	X	X	X
Ask how you are feeling generally	X	X	X	X
Request to return the e-Diary or assist to delete the app				X

E-Diary

Some participants were asked to complete a vaccination diary in the e-Diary for 7 days following previous study injections. In this part of the study a vaccination diary is not needed.

Convalescent Visit

You may remember that you were asked to attend an extra visit (i.e., convalescent visit) to the study site about a month after any potential COVID-19 illness visit. Now, the study team has obtained enough clinical data in the study from these convalescent visits, it is no longer a requirement for you to attend this extra visit after the potential COVID-19 illness.

Study Vaccine (BNT162b2) Risks:

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

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

Very common (occurring in more than 1 in 10 people): injection site pain, injection site swelling, fatigue (tiredness), increased body temperature (fever, more common after the second dose), chills, headache, diarrhea, joint aches, and muscle aches.

Common (between 1 in 10 and 1 in 100 people): feeling sick (nausea), being sick (vomiting), and injection site redness.

Uncommon (between 1 in 100 and 1 in 1,000 people): enlarged lymph glands, allergic reactions (symptoms may include rash, itching, hives), decreased appetite, lethargy, sweating and night sweats, pain in arm, and feeling weak or unwell.

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

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

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received BNT162b2. Cases have mainly been reported in males under 30 years of age and following the second vaccination, however, there have been some cases reported in older males and females as well as following the first vaccination. The chance of having this occur is very low and, in most of these people, symptoms began within a few days to a week following vaccination. As a precaution, you should seek medical attention right away if you have any of the following symptoms after receiving the vaccine:

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

Please also notify study staff, when appropriate, if you have any of these symptoms. You may need to come in for an extra visit or have some follow-up tests if you have any of these symptoms.

Whilst some severe cases have been reported, most cases have been associated with full resolution of symptoms in the short term, however, long-term follow-up is limited. It is not known whether the risk of myocarditis or pericarditis is increased following additional doses of the vaccine, e.g., following a booster dose.

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

As in all research studies, the COVID-19 vaccine may involve risks that might be expected based on results from studies of similar vaccines, as well as risks that are currently unknown.

Therefore, it is important that you report all symptoms and side effects that you experience as soon as they occur, whether or not you think they are caused by the study vaccine.

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

If I catch COVID-19 disease, could the vaccine make it worse?

For some other vaccines tested in animals against similar viruses (but not the coronavirus that causes COVID-19), there have been reports of the illness being more severe in the animals that received the vaccine than in those that did not. So far this has not been seen with BNT162b2. It remains important for you to contact your study doctor if you develop symptoms that might be caused by COVID-19 (for example, fever, cough, shortness of breath).

Please take as much time as you need to ask questions from the research study team before agreeing to continue. If after receiving this information you agree to receive the booster dose as part of this research study, please sign and date below.

	CLINICAL STUDY INFORMED CONSENT ADDENDUM	Page: 7 of 9
Protocol Number: C4591001	**Associated ICD Version Date**: Phase 2/3, Adult ICD (02Jul2021)	**ICD Addendum Version Date**: Third Dose of BNT162b2 (08Sep2021)

SIGNATURES:

- I have read the information in this addendum to the informed consent document.
- I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction.
- I have been given enough time to decide whether or not I want to receive the booster dose as part of this research study.
- I voluntarily agree to receive the booster dose as part of this research study.
- I do not give up any of my legal rights by signing this consent addendum.
- I have been told that I will receive a copy of this signed and dated addendum.

SIGNATURE LINE TO BE COMPLETED FOR AN ADULT PARTICIPANT:

_____
Printed name of participant

_____ _____
Signature of participant Date of signature[§]

Person Obtaining Consent:

_____
Printed Name of the Person Conducting the Consent Discussion

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

	CLINICAL STUDY INFORMED CONSENT ADDENDUM	Page: 8 of 9
Protocol Number: C4591001	**Associated ICD Version Date**: Phase 2/3, Adult ICD (02Jul2021)	**ICD Addendum Version Date**: Third Dose of BNT162b2 (08Sep2021)

SIGNATURE LINE(S) TO BE COMPLETED FOR A CHILD PARTICIPANT:

Assenting Instructions:

- All children are required to assent, unless the study doctor determines that the capability of the child is so limited that the child cannot reasonably be consulted.
- If assent is obtained, have the person obtaining assent document assent on the assent form.

Please check one box below to show whether or not you want to be in this study.

☐ **Yes, I want to be in this study.**

☐ **No, I do not want to be in this study.**

_____
Printed Name of Child/Young Person

_____ _____ _____
Child/Young Person Signature Date Time

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

☐ I am the biological or adoptive parent of the child.

☐ I am the legal guardian of the child.

_____
Printed Name of Parent / Legal Guardian (Individual Authorized to Consent to the Child Participant's General Medical Care)

_____ _____
Signature of Parent / Legal Guardian Date of signature[§]

	CLINICAL STUDY INFORMED CONSENT ADDENDUM	Page: 9 of 9
Protocol Number: C4591001	**Associated ICD Version Date**: Phase 2/3, Adult ICD (02Jul2021)	**ICD Addendum Version Date**: Third Dose of BNT162b2 (08Sep2021)

Statement of person conducting assent discussion:

1. I have explained all aspects of this addendum to the informed consent document to the participant to the best of his or her ability to understand.
2. I have answered all questions of the participant relating to this addendum.
3. I believe the participant's decision to provide assent is voluntary.
4. If the participant decides to provide assent, the study doctor and study staff agree to respect the participant's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

_____
Printed Name of the Person Conducting the Assent Discussion

_____ _____ _____
Signature of the Person Conducting Assent Discussion † Date of signature Time (for Assent)

§Participant/parent/legal guardian must personally date their 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 addendum during the same interview when the participant/parent/legal guardian signs and date the addendum.