Research Study for a COVID-19 vaccine in Healthy Children and Young Adults Phase 2/3 Lower Dose Evaluation

We would like to tell you about a research study and see if you would like to take part.

You will need to read this information and then decide if you would like to be in this research study.

This research study is to find out if a new COVID-19 vaccine is safe and if it works in children and young adults.

The study doctor and nurses will explain the study and answer any questions that you have. You can circle or highlight things on this paper that you want to know more about. If you don't understand something, just ask us. It is okay to ask questions now and anytime later that you think of them.

This document is called an ***assent form***. If you have any doubts, concerns or worries please tell your study team. You can discuss this information with your family and friends if you want to.

If you are willing to be in this study, we will ask you to sign and date this assent form. If you don't want to take part that's OK – no one will be mad at you.

WHY ARE WE DOING THIS STUDY?

In 2019 a new germ (coronavirus) started making adults and children ill with a disease called COVID-19. Scientists and doctors have been working to make a vaccine that can help protect adults and children against this coronavirus. Scientists and doctors have already done some research studies in healthy adults and children and there are now a few vaccines that are allowed to be given to healthy adults and some older children.

In this research study we are looking at how well one of these vaccines (called BNT162b2) works in children like you and young adults. We want to find out if BNT162b2 can help protect children and young adults against COVID-19.

WHAT HAPPENS IN THE 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 will be conducted in several steps. The study will only progress if the data collected suggests it is safe to do so. The steps in the study are detailed below.

The steps in the study are detailed below. **You are being asked to take part in the Phase 2/3 Lower Dose Evaluation** step of the study.

Phase 1 Lower Dose Evaluation will be carried out in 3 age groups. **Every participant in this Phase will receive two injections of the active study vaccine.** The following age groups will take part in this step of the study:

- 16 to less than 30 years of age,
- 12 to less than 16 years of age, and
- 5 to less than 12 years of age.

The remaining step of the study will be the **Phase 2/3 Lower Dose Evaluation.** In this part we will use a dose level selected from the Phase 1 part of the study. This step of the study will collect information from a larger number of children and young adults about the safety of the vaccine and the amount of antibodies produced by the vaccine. In this part of the study all participants will receive active vaccine. The age groups taking part in this step of the study will be:

- 16 to less than 30 years of age,
- 12 to less than 16 years of age, and
- 5 to less than 12 years of age.

Please note that this part of the original study called **Phase 1 Dose Finding has been completed**. There were 3 age groups in this part and the study looked at up to 3 dose levels in each age group. The children in this part of the study were:

- 5 to less than 12 years of age,
- 2 to less than 5 years of age, and
- 6 months to less than 2 years of age.

Phase 2/3 Selected Dose is currently ongoing, and the dose level was selected from the Phase 1 part of the study. This step of the study will collect information from a larger number of children about the safety of the vaccine and the amount of antibodies produced by the vaccine. In this Phase, all participants will receive either active vaccine or placebo. The children in this step of the study will be:

- 5 to less than 12 years of age,
- 2 to less than 5 years of age, and
- 6 months to less than 2 years of age.

This assent is for **Phase 2/3 Lower Dose Evaluation** and there will be about approximately 96 children less than 16 years old, and about 64 participants 16 to less than 30 years of age taking part in this Phase.

The total number of adults and children taking part in the study will depend on the results seen during the study.

Everyone will be in this research study for about 7 months.

Study Vaccines

Once the study doctor has confirmed that you meet the study requirements, you will be assigned your study vaccine.

Phase 2/3 Lower Dose Evaluation of the study is an "open-label phase", which means in this step all participants will receive active study vaccine.

All children/young adults in an given age group will receive the same dose of vaccine. The dose will be chosen based on the results from the earlier phases of the study. It is possible that the different age groups may be given different dose levels. There will be 300 participants in each age group that will be given their dose level. The age groups in this part of the study are:

- 16 to less than 30 years of age,
- 12 to less than 16 years of age, and
- 5 to less than 12 years of age.

The vaccine will be given to you through an injection into the muscle in your upper arm. Each participant will receive two injections of vaccine, approximately three weeks apart. On the days you receive your vaccine injection, you will be asked to wait with your child at the study site for at least 30 minutes for observation.

During the study:

- You will come to the research site for visits.
- We will collect a blood sample at 3 visits. The amount of blood taken at each visit will depend how old you are and will be either 10ml (2 teaspoons) or 20 mL (4 teaspoons).
- We will give you 1 injection at visit 1 and 1 injection at visit 2.
- We will also collect a nose swab from your nose at visit 1 and visit 2.
- You may have to come for extra visits and tests if your doctor thinks they need to see you.
- The whole study will last about 7 months.
- You or your Mom/Dad/guardian will have to answer some questions about you on a smart phone/ APP (called an e-diary).

We will work with your mom or dad or your guardian on scheduling these visits around your activities like school. We will contact your mom or dad or guardian once or twice by phone to ask about your health.

There are 3 sorts of visits in the study. Vaccination visits, checkup visits and extra visits if you get any have a reaction after your vaccination. The table below shows you when these visits will take place and what will happen.

For the participants taking part in **Phase 2/3 Lower Dose Evaluation**, the study doctor or nurse will perform following assessment and procedures:

Visit Number	**1**	**2**	**4**	**5**
Visit Description and Visit Timing	**Study Vaccine 1 Visit**	**Study Vaccine 2 Visit**	**1-Month Follow-up Visit**	**6-Month Follow-up Visit**
Review and sign informed consent document	**X**			
Ask about medical history as well as date of birth, sex, race and ethnicity	**X**			
Measure pulse rate, respiratory rate, blood pressure, and body temperature	**X**	**X**		
Perform a physical exam, including measurement of height and weight (height at weight information will be collected at 1st visit only).	**X**	**X**		
If you are female and if needed, you will be asked to provide a urine sample for a pregnancy test	**X**	**X**		
If needed, will discuss the use of appropriate birth control with you	**X**	**X**	**X**	
Ask about medications you are currently taking		**X**	**X**	**X**
Ask about any other vaccines you have been given	**X**	**X**	**X**	**X**
Check you meets all the study requirements	**X**	**X**		
Take a nasal swab for the detection of virus causing COVID-19	**X**	**X**		
Collect blood sample (up to 20 mL) to test antibody levels	**X**		**X**	**X**
Give vaccine injection in your arm and observe for 30-min following injection	**X**	**X**		
Thermometer & measuring device will be provided. e-diary will be provided or app downloaded	**X**	**X**		
You will be asked to complete vaccination e-diary for 7 days to record potential side effects following each vaccination	**X**	**X**		
Ask how you are feeling	**X**	**X**	**X**	**X**

WHAT ARE THE POSSIBLE UNCOMFORTABLE OR HARMFUL THINGS THAT COULD HAPPEN WHILE I'M IN THIS RESEARCH STUDY?

You may feel tired or embarrassed by the questions the study doctor or nurse asks you.

If you are girl and have to give a wee (urine) sample you may feel embarrassed.

When you have your nose swab taken it might be painful or your nose might bleed a bit.

When you have a blood sample taken it may:

- Hurt when the needle goes into your arm.
- Cause a red spot or bruise on your arm or your arm might feel sore.
- Make you feel dizzy.
- Cause an infection at the place where the needle went into your arm.

When you are given your vaccination it could hurt where the needles goes in your arm.

- It could also make your arm red or swollen.
- You might also feel sick or be sick.
- You might get a headache, get pains in your muscles or joints or feel tired.
- You might get chest pain, shortness of breath, or feelings of having a fast-beating, fluttering or pounding heart. You may need to come in to see the study doctor for further assessments if you have these symptoms.
- You might also get a temperature, feel shivery or cold.
- You could have an allergic reaction, which means you could have swelling of the face, or lips. Other allergic reactions may include rash, hives or itching.

You might also feel unwell in other ways. Remember to tell your parent(s) or your guardian(s) and the study doctor everything you are feeling while you are in the study including if you feel sick.

DO I NEED TO USE BIRTH CONTROL?

If you are a girl, and have started to have periods, the study doctor or nurse may test your urine to make sure you are not pregnant. The doctor or nurse will tell you if the test results show you are pregnant. Depending on the laws of your area, the study doctor or nurse may also tell your parent(s) or your guardian(s) about the results of the pregnancy test.

If you are a girl or boy who is sexually active, you must use birth control during the study and for at least 28 days after your last vaccination. If appropriate your study doctor will talk to you about this and explain your options.

If you are pregnant, planning to become pregnant or are breast feeding a baby, you cannot be in the study as there may be risks to the unborn baby or nursing baby. Nobody knows what these risks are right now.

If you think you are pregnant during the study, you must tell the study doctor immediately. If you become pregnant, you will have to leave the study. The study doctor may ask for information about the pregnancy and the birth of the baby. The study doctor may share this information with others who are working on this study.

If you are a boy, and you think that you may have gotten a girl pregnant while you are in the study, you must tell your study doctor immediately. The study doctor may ask for information about the pregnancy and the birth of the baby. The study doctor may share this information with others who are working on this study.

WHAT OTHER OPTIONS ARE THERE?

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

Participation is voluntary and **you do not have to be in the study if you don't want to.**

It is your choice if you want to to be in this study or not. No one will be mad if you choose not to take part.

If you leave the study, you may be asked to come in for one last visit.

WHAT IF I HAVE QUESTIONS?

You can ask questions about the study any time. You can call the study doctor any time. If you want to ask questions about what it means to be in a research study, you or parent(s) or your guardian(s) can call [insert IRB/IEC name] (a group of people who review the study to protect your rights) at [insert IRB/IEC number].

For you to be in this study, you and your parent(s) or your guardian(s) must agree to you being in it. But it is still up to you if you *want* to do it.

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

Statement of person conducting assent discussion:

1. I have explained all aspects of the research 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 research.
3. I believe the participant's decision to enroll or not enroll is voluntary.
4. If the participant decides to enroll, 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 Person Obtaining Assent: _____

Signature of Person Obtaining Assent: _____ Date: _____ Time: _____