



CT05-GSOP-
RF15 1.0

**PHASE 2/3 CLINICAL STUDY ASSENT
TEMPLATE FOR YOUNGER CHILDREN**

15-Feb-2021

Assent Version Date: 06 Aug 2021 | Assent Version Number: 3 Assent Level: Study (Phase 2/3 **Placebo Controlled Selected Dose**)

Site #: N/A | Protocol No. C4591007 | Protocol Date: 06 August 2021 Country: N/A | Derived From: 05 Mar 2021

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The official version of this form is located in the electronic document management system.
This document was created based on QMS04-GSOP-SD-GL06 5.0 CMCD Forms Template WORD 01-Oct-2020.
TMF Doc ID: 173.16 (Study); 173.10 (Country/Central); 173.20 (Site)

Research Study for a COVID-19 vaccine in healthy children and young adults
(Phase 2/3 Evaluation of Placebo Controlled Selected Dose)



Hello there! I'm Doctor [NAME OF THE PI] and I want to understand if COVID-19 vaccine can help prevent children and young adults from getting a germ (called coronavirus) that can make them sick with the COVID-19 disease.

This is called a research study. A research study is when doctors work together to try to see if the vaccine is safe and if it is can help people from becoming sick.

My nurses and I will describe the study to you and your mom or dad or your guardian and we will answer any questions that you have. You can ask to read the information given to your mom or dad or your guardian about the study. After you learn more about the study and if you want to be in this study, I will ask you to sign this paper.

You can ask questions whenever you want to.



Doctor, I have a question for you. If I want to be in the study, what will I need to do?

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Page 2 of 9

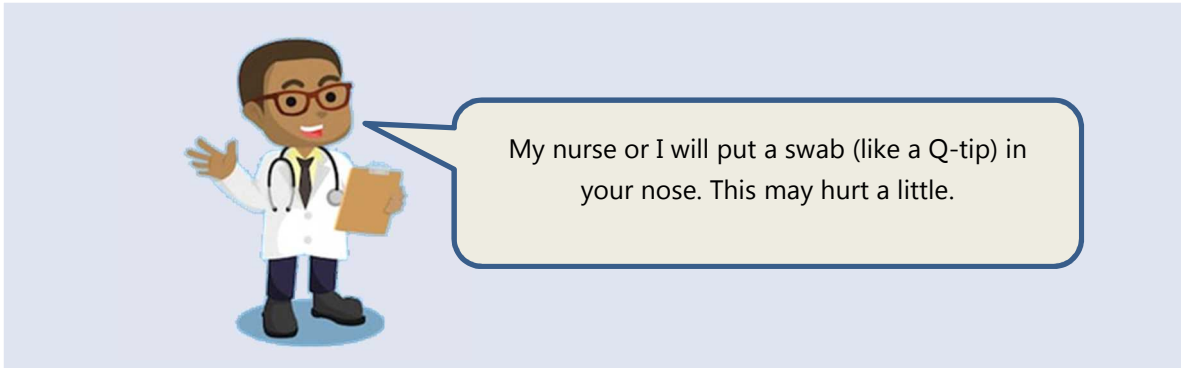
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Well, good question! We will start with a visit where we will ask your mom or dad or guardian some questions about your health. Then I will do a physical examination (like a checkup; measure your height, weight, pulse, blood pressure and temperature). Then my nurse or I will ask you to have some tests done.



If you are a girl, we may ask for your urine to perform a pregnancy test, if my nurse or I determine it is necessary.



My nurse or I will put a swab (like a Q-tip) in your nose. This may hurt a little.

My nurse or I will take a little bit of your blood with a needle from a vein in your arm. This may hurt a little.



You will need to get 2 or 4 vaccine injections (shots) during the study. You may feel a little prick from the needle when you get these shots. We will take your temperature before you get the shots to make sure you don't have a fever.

After your shots, you will need to stay at the doctor's office for at least 30 minutes so that my nurse or I can make sure you are okay.



In the next few days after your shots, your arms may become red, puffy, or sore. You might also feel a bit achy or tired, and you might get a fever. If any of these things happen, you should tell your parents or your guardian and the doctor. Your mom or dad or guardian will complete an electronic diary about how you are feeling for 7 days after you receive each vaccine shot.

At any time while you are still taking part in the study, if you get sick, your parent or guardian may need to contact your doctor.



And how many times do I have to come to see you, Doctor?

That is a great question!
You will come to my clinic/hospital for 3 to 5 visits.

- We will take some blood sample from a vein in your arm at least on 2 planned visits. You may have an additional blood sample taken from a vein in your arm at one more visit.
- We will give you first shot at visit 1 and a second shot at visit 2. These shots will be given approximately three weeks apart.
- We will also take a nose swab at each visit where you receive a shot.
- We will tell you and your parents/guardian 6 months after your second shot, if you were given the COVID-19 vaccine at Visit 1 and Visit 2. If not you will be offered 2 more shots approximately three weeks apart.
- The whole study will last about 2 years.

We will work with your mom or dad or your guardian on scheduling these visits around your activities like school. Your mom or dad or guardian will also be contacted up to 4 times by phone to ask about your health, 2 of these times, we may ask them to bring you for a visit at my clinic/hospital. You may have to come for extra visits and tests if your doctor thinks they need to see you.

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What might happen after each of these visits to the clinic/hospital?



While you are in the study, tell the doctor or your mom or dad or your guardian if you feel sick. There is a chance that during the study you could feel pain, feel bad or uncomfortable.

The shot could cause:

- Redness, swelling, or pain where the needle goes in.
- Headache, tiredness, fever, chills, muscle pain, joint pains, feeling sick (nausea).
- It is possible that you might get chest pain, shortness of breath, or feelings of having a fast-beating, fluttering or pounding heart. You may need to come to the clinic/hospital (doctor's office) if you have these symptoms.

Other things that could happen:

- If you become sick during the study, we may require your mom or dad or guardian to bring you to the clinic/hospital or may ask them to take a nose swab from your nose at home.

This study will help us make better vaccines so that other children like you could benefit from information we learn in this study.



Now it's up to you if you want to be in this study. No one will be mad if you do not want to be in the study or if you want to stop being in the study at any time.

If you say okay now and you change your mind about it later, just tell me or one of my nurses or your mom or dad or your guardian.

If you have any questions you can have your mom or dad or your guardian call me or one of my nurses.

[provide the contact information for the PI]

PLEASE PUT AN "X" MARK IN THE BOX NEXT TO THE PICTURE THAT SHOWS YOUR DECISION OF WHETHER OR NOT YOU WANT TO BE IN THIS STUDY

YES, I want to be in the study:



NO, I do not want to be in this study:



Sign your name (age appropriate)

Printed First and Last Name of Child: _____

Statement of person conducting assent discussion:

1. I have explained the research study to the participant to the best of his or her ability to understand.
2. I have answered all the questions of the participant relating to this research study.
3. In my judgment, 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 First and Last Name of Person Obtaining Assent:

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

Phone number Of Person Obtaining Assent : _____

Study Site Team Instructions: Only complete the section below if assent is required, and either only verbal assent was obtained from the participant or assent was not obtained from the participant.

Please check appropriate box and sign below.

The undersigned, _____, hereby certifies that verbal assent was obtained from the participant.

Assent was not obtained from the participant. (Please state the reason. Examples include: participant lacks cognitive abilities to understand the information.)

Date: _____

Time: _____

Signature: _____

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