



CT05-GSOP-
RF15 1.0

PHASE 1/2/3/4 CLINICAL STUDY ASSENT
TEMPLATE FOR YOUNGER CHILDREN

15-Feb-2021

Assent Version Date: 09 Aug 2021 | Assent Version Number: 1

Assent Level: Study (**Phase 1 Evaluation of Lower Dose Levels**) Younger children

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

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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)FDA-CBER-2021-5683-1076724

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Research Study for a COVID-19 vaccine in Healthy Children and Young Adults
Phase 1 Lower Dose Evaluation



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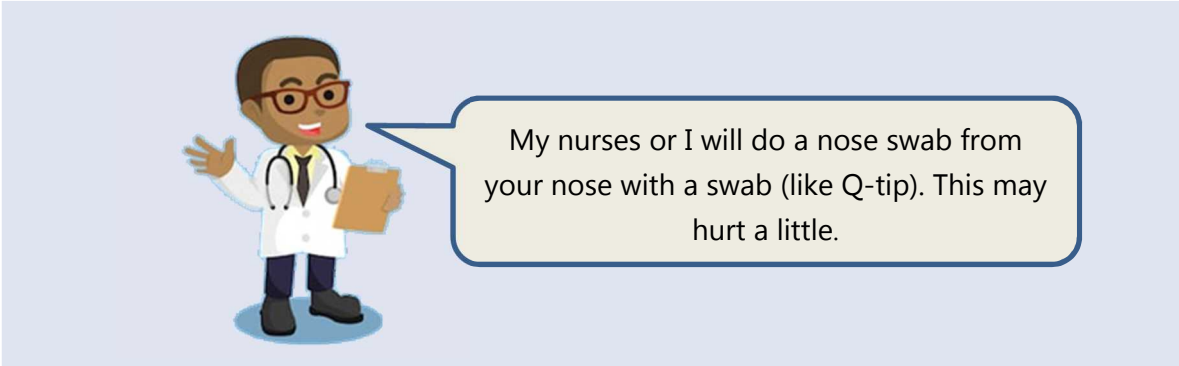
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Well, good question! We will start with a visit where we will ask your mom or dad or guardian some questions about your health. Then I will do a physical examination (like a checkup; measure your height, weight, temperature, pulse and blood pressure).



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



My nurses or I will do a nose swab from your nose with a swab (like Q-tip). This may hurt a little.

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



VACCINATION TIME



You will need to get a total of 2 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 clinic/hospital (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 vaccine injections, your arms may become red, puffy, or sore. You may also feel a bit achy or tired, and you might get a fever.

If any of these things happen, you should tell your parents 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 injection.

If you feel sick while you are in the study you must tell your mom or dad or guardian who 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 or 4 visits.

- We will collect a blood sample at the first 3 visits.
- 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.
- The whole study will last about 7 months.

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 once or twice by phone to ask about your health.

You may have to come for extra visits and tests if your doctor thinks they need to see you.



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 injection could cause:

- Redness, swelling, or pain at the injection site
- 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.

Other things that could happen:

If you become sick during the study, we may need your mom or dad or guardian to bring you to the clinic/hospital.

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 (if age appropriate)

Printed First and Last Name of Child: _____

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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: _____