

NCT#: 04852276**PRINCIPAL INVESTIGATOR:** Emily E. Ricotta, PhD, MSc**STUDY TITLE:** Analysis of the immune response to COVID-19 vaccination and outcomes in individuals with and without immune deficiencies and dysregulations**STUDY SITE:** NIH Clinical Center (CC)

Cohort: Assent

Assent Version: August 13, 2021

What is a research study?

Research studies help us learn new things. We can test new ideas. First, we ask a question. Then we try to find the answer.

This paper talks about a research study that we are doing and the choice that you have to take part in it. You are being asked to join this research study because you either have health problems with your immune system or you do not, and you are going to get a COVID-19 vaccine. We want you to ask us any questions that you have. You can ask questions any time.

Important things to know...

- You get to decide if you want to take part.
- You can say 'No', or you can say 'Yes'.
- No one will be mad at you if you say 'No'.
- If you say 'Yes', you can always change your mind and say 'No' later.
- You will still be able to get good care from a doctor no matter what you decide.

Why are we doing this research?

We are doing this research to learn about how well COVID-19 vaccines work in people with immune system problems. The immune system is the part of the body that fights germs to keep people healthy. People with immune system problems cannot fight germs as well as people without these problems. Vaccines work by helping the immune system learn to fight new germs, like the germ that causes COVID-19. Since people with immune system problems can have trouble fighting germs, we want to know how well the vaccine works to help them fight COVID-19.

What would happen if I join this research?

If you decide to be in this research study, we would ask you to do the following:

- Blood draws: Some blood will be taken from your arm using a needle. This will be done 1 time before you get your COVID-19 vaccine, and 1 time after each vaccine you get. The amount of blood taken each time will be between 1 and 2 tablespoons. The blood can be taken at the NIH or at a doctor's office or laboratory. If you cannot go to these places, your parent can take a few drops of blood by sticking your finger with a needle. They will collect the drops of blood on a piece of paper and send it to us in the mail. If you agree, you can also have blood taken up to 7 more times for this study. If you get more COVID-19 vaccines and agree to stay in the study, this could be more.
- Questions: We will ask you and your parents to answer some questions online. The questions are about your health and how you felt after getting the vaccine.
- Saliva (spit) collection: If you agree, you can send us saliva samples. To do this, you would spit into a cup or tube. Then your parents would send it to us in the mail. You would do this about 2 times each month for about 6 months while you are in this study. If you get more COVID-19 vaccines, this time could be longer. You can still be in the study if you do not want to do this.

If you join this study, you would be on the study for at least 1 month after your last COVID-19 vaccine. If you agree to give extra blood, you could be on the study for up to 2 years after your last vaccine. If you get extra COVID-19 vaccines and agree to stay in this study, this time could be longer.

Would anything in this research study hurt or bother me?

Taking blood from your arm using a needle can hurt. Sometimes the needle can leave a bruise on the skin. Sticking your finger with a needle to collect blood can hurt, too.

There is a small chance that other people may see your answers to the questions we ask you.

You can say 'no' to what we ask you to do for the research at any time and we will stop.

Could the research help me?

This research will not help you. We hope to learn about how well the COVID-19 vaccine works in people with immune system problems. This will help other people in the future.

What else should I know about this research?

If you want to stop being in this study, please tell the research doctors.

PATIENT IDENTIFICATION**Assent to Participate in a Clinical Research Study**

NIH-2977-1 (7-19)

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To thank you for being in the study, we will give you between \$10 and \$50 each time you have blood taken. We will give you \$5 each time you send us a saliva sample. You should talk with your parents about how you would like to use this.

What if I have any questions?

You can ask questions any time. You can talk to Dr. Ricotta or another person from the study team. Ask us any questions you have. Take the time you need to make your choice.

Is there anything else?

If you want to be in the research study after we talk, please write your name below. We will write our name, too. This shows we talked about the research and that you want to take part.

Assent of Participant:

Signature of Participant

Print Name of Participant

Date

Investigator:

Signature of Investigator

Print Name of Investigator

Date

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