

THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION
Icahn School of Medicine at Mount Sinai,
Mount Sinai Beth Israel, Mount Sinai St. Luke's, Mount Sinai West

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Form Version Date: 10/30/2020

TeleKidSeq: Incorporating Telehealth into the Clinical Care of Diverse NYC Children Undergoing Whole Genome Sequencing

What is this about?

I want to tell you about a research study we are doing. A research study is a way to learn information about something. We would like to find out more about how genomic testing can help children and young adults with rare diseases. This study will also help scientists learn how best to perform genetic testing in people from diverse backgrounds. We also hope to help medical teams learn the best way to talk with families about genomic testing. To get the information for the study we will talk to about 500 families like yours. You are being asked to join the study because your doctor at Mount Sinai or private practice thinks that there may be a genetic reason for your epilepsy, developmental delays, heart disease, or a low immune system. The researcher in charge of this project is called the "Principal Investigator." Her name is Dr. Eimear Kenny.

What do you want me to do for the study?

If you agree to be part of this study, we will ask you and your parents to meet with us via telehealth (videoconference such as Zoom), at least three times over the next 9 months or so; each visit will last one to two hours.

At your first visit, you will meet a genetic counselor. A genetic counselor is a person who is trained to speak with families about genetic testing. He or she will explain to you the types of tests we will do on you and your parents' blood, and how it may help us learn the cause of your condition. They will also ask you and your parent(s) questions about what you want to know and learn from this test. You and your parents will also be asked about your family's health history and about your health. The genetic counselor will walk you and your parents through how to collect saliva or cheek cell (buccal) samples from yourselves and mail it to the lab. What we learn from you will help us understand your test results. Towards the end of this visit, your parents will be asked to answer a few questions about your meeting with the genetic counselor. If for whatever reason you are unable to collect a saliva or buccal sample, study staff will arrange for you to come in person to collect a blood sample from you and your parent(s).

Three months after this, you will have your second visit with the genetic counselor where you will learn about the results of your test. At the end of the visit, your parents will be asked to answer a few questions about what you learned from your results.

About nine months after your first visit and six months after your return of results session, your parent(s) will have another study visit. The point of this visit is to see how well they understood your results, a measure for us to see how well we communicated the results. This visit will involve completing the third and final survey, and can be done over the phone.



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What will happen with your genomic data?

Your parents will decide if they want to share your genomic data and/or sample with other scientists so they can learn more about how genetic changes affect health. If your parents choose to share your data in secure, public research databases, any way to identify you (such as your name, date of birth, etc.) will be removed from the data before it is shared. Data sharing usually happens within six months after signing up for the study. If your parents have decided to share your data, but when you turn 18 you decide that you would NOT like your data to be shared, please contact our team at 212-659-9571, so we can check the status of your data/sample. If it has not yet been shared, we can stop the sharing. If your data/sample has already been de-identified and shared, it is likely that we will not be able to retrieve it.

What things may bother you about being in this study?

You may feel some pain when getting your blood drawn, but that will go away. You and/or your parent(s) may learn something from your genetic test that can make you feel upset. We hope that you will talk about any of your feeling with the genetic counselor or your study doctor.

Will the study help me in any way?

We do not know if being in the study will help you, but we may learn more about what is causing your condition. The information we learn from the study may also help your doctors find a better medicine for you. You will be helping us learn how to best use this type of test to help other children like you.

Do I have to be in the study?

You do not have to join this study. It is up to you and your parents. No one will be mad at you if you say no to the study. You can say okay now, and you can change your mind later. All you have to do is tell us.

Do you have any questions?

You can ask any questions that you have about this study. If you have a question later that you did not think of now, you can call me at 212-659-9571, or ask me next time.

We will keep your information private.

The only people who will know about what you tell us in this study is the people who work on the study, your doctors and your parents. We will not tell anyone else what you say or do in the study.

We will not tell your parents about the results of your pregnancy test unless you give us permission to tell them.

