

**University of North Carolina-Chapel Hill
Assent Form 2; Child Subjects ages 7-14
Assent to Have a Blood Test Called “Genomic Sequencing”
Biomedical Form**

IRB Study # 17-1806

Consent Form Version Date: 02-28-2018

Title of Study: North Carolina Clinical Genomic Evaluation by Next-gen Exome Sequencing, phase 2 (NCGENES 2)

People in Charge of the Study: Jonathan Berg, MD, PhD, Bradford Powell, M.D., PhD, Christine Rini, Ph.D.

Where they work at UNC-Chapel Hill: School of Medicine, Department of Genetics

Study Contact: Jeannette Bensen, PhD

Study Contact telephone number: XXXX

Study Contact email: XXX

You and your parents have already agreed to be in the NCGENES research study. We have divided the families who have joined the study into 2 groups. Half of the families who join the study are in Group 1 and half are in Group 2. You and your family are in Group 2.

Why are we asking you and your parents to decide if you should have a blood test?

We are asking the families who are in Group 2 whether or not they want their child to have a new blood test called “genome sequencing.” Your parent needs to say it is OK for you to have this test. You do not have to have this test if you don’t want to, even if your parent has already said that it is OK.

Why are we doing this study?

We are doing this study to see if using a newer blood test is better than using older blood tests to find out why some children have a medical condition like yours.

How will the test work?

In our bodies, we have instructions about how we should grow and develop. These instructions are called *genes*. Sometimes there are mistakes in our genes that can cause us to have medical problems like the ones you have. We can do blood tests to help us look for mistakes in a person’s genes.

We think that the newer test might find mistakes in a person’s genes faster than older tests are able to do. But it is possible that the newer test will not find mistakes any faster than the older tests. If we find mistakes in a person’s genes faster, it may help them get better care from their doctor.

This form has information about this new blood test. After reading it, we will ask you and your parents to decide if you should have this test or not.

These are some things we want you to know about this blood test.

Sometimes good things happen to people who have this test, and sometimes things happen that they may not like. We will tell you more about these things later in this form.

What will happen if you and your parents agree for you to have this blood test?

If you and your parents agree for you to have this test, we will need for you to let us use a needle to take a little bit of blood (1-2 teaspoons) from the inside of your arm.

What will happen to the blood that we take?

From the blood we take, we will look at the chemical that makes up the genes. It is called DNA. We want to look at the DNA that makes up your genes to see if we can find out more about why you have certain health problems. In addition, in a very few people, this test might find other mistakes in the DNA that tell us a person might have other medical problems in the future. If we find these mistakes in your DNA, it will be important for your parents to know about them to help keep you as healthy as possible.

Who will be told the things we learn about you from the blood test?

If we find a mistake in your DNA that explains health problems that you have or that explains a chance that you might have certain health problems in the future, then we put a report of this information in your medical record. Your medical record has information about your doctor visits. This information is important to help your doctors take care of you. No one else will be able to see what we found by the test unless you and your parents let them.

This test will not tell us if you are pregnant or if you have done anything against the law. It also will not tell us if you have mental illness. We will not tell anyone what you tell us without your permission unless there is something that could be dangerous to you or someone else.

We are learning more about genes and the DNA they are made of. We will look at your DNA again later in the study to see if we can find out anything new. If we find anything new that is important for your health, your parents will be told and, if your parents agree, the new information will also be put into your UNC medical record.

What are the good things that might happen?

There is a small chance that the information we learn from the test will help your doctors take better care of you.

What are the bad things that might happen?

We need for you to let us get some blood from you to do the testing. We will need to poke your arm with a needle to get the blood. This can make a bruise and may hurt for a minute.

Sometimes learning more about your health can make you sad or worry. Your parents can also feel sad or worried. The doctors and your family will help explain what this test means for you.

Other things may happen that the people in charge of the study don't know about. You should report any problems to the people listed on the front page of this form.

Will you get any money for having this test done?

No. We will not pay you for letting us draw some of your blood for the test.

Will you be charged for having this test done?

No. We will not charge you or your parents for this test.

Who should you ask if you have any questions?

If you have questions you should ask the people listed on the first page of this form.

If you have other questions, or if you want to complain about the study, you may contact the Institutional Review Board at 919-966-3113 or email them at IRB_subjects@unc.edu. They are the people who are in charge of making sure we follow all the rules when we run this study. You do not have to use your name.

Other researchers in other places may want to use the some of the blood sample or some of the information we learned from your blood sample. They would use this sample or information to try to learn new things. There is a place called a “data bank” where we can send some of your blood sample or information we learned from it for other researchers to use. The databank has many ways to keep your information private. Any information that we send to the databank will be labeled with your special ID number and not your name. When you turn 18, we will remove the link between your special ID number and your name so that your study information can no longer be linked back to you.

Participant Agreement:

I have read the information provided above and I have asked all the questions I have at this time. I voluntarily agree to be in **the North Carolina Clinical Genomic Evaluation by Next-gen Exome Sequencing, phase 2** (NCGENES 2) study. **Principal Investigators:** Jonathan S. Berg, MD, PhD, Bradford Powell, M.D., PhD, Christine Rini, Ph.D.

If you sign your name below, it means that you agree to have this test

Sign your name here if you agree to have this test

Date

Print your name here if you agree to have this test

Signature of Research Team Member Obtaining Assent

Date

Printed Name of Research Team Member Obtaining Assent