University of North Carolina-Chapel Hill
Assent Form 1; Child Subjects ages 7-14
Assent to Participate in a Research Study (Randomization to 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)
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Study Contact telephone number: XXXX
Study Contact email: XXX

The people listed are doing a research study. Research studies try to learn new things that may help people in the future.

Your parents have already joined the first part of the NCGENES study. We are now asking you and your parents if you want to join the second part of the study.

Your parent needs to give permission for you to be in this study. But you do not have to be in this study if you don't want to, even if your parent has already said it is OK.

You may stop being in the study at any time. If you decide to stop, no one will be angry or upset with you.

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

Why are we doing this research 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 many people will take part in this study?

We think that about 850 families will join this part of the study.

What will happen if you take part in the study?

We will ask your parent to let us see some of the information that is in your medical record.

We will divide the families who join the study into 2 groups. Half of the families who join the study will be in Group 1 and half will be in Group 2. After your parents and you agree to being in this part of the study we will tell you which group you are in.

If your family is in Group 1: You will get the same care from your doctors as any child who is not part of the NCGENES study would get. The doctor will do a physical exam and may say that you need to have more tests.

If your family is in Group 2: You will get the same care from your doctors as any child who is not part of the NCGENES study would get. The doctor will do a physical exam and may say that you need to have more tests. In addition, you and your parents will be told about a newer blood test we are using to find out why some children have a medical condition like yours. We will ask your parents if they want you to have this test. If they want you to have the test, we will ask you if that is OK with you. If they don't want you to have this test, that is OK too.

Your family will probably see the doctors again to talk about any tests that you had done at your first visit. We will check on your health by using your medical records until you turn 18 years old.

In the future, if we learn new things that might change how your doctors are caring for you, we will contact your parents.

In the future, we may also ask if you and your parents want to join other research studies. You can say yes or no to these future research studies when we ask you.

Who will be told the things we learn about you in this study?

We do many things in this research study to help keep the information we gather about you safe and private, so other people cannot see it. For example, we will give you an ID number. We will use this number instead of your name when we share information about you.

Other researchers in other places may want to use information that we get from you and your parents in the NCGENES study to learn new things. There is a place called a "databank" where we can send information 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.

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.

What good things might happen to you if you join the study?

We don't expect that good things will happen to you by being in this part of the research study. It is possible that your being in this study may help us learn about how to use the newer blood test with patients in the future.

What bad things might happen to you if you join the study?

We don't expect that bad things will happen to you by being in this part of the research study. Things may happen that the people in charge of the study don't know about. You or your parents should report any problems to the people listed on the front page of this form.

Can you stop before your part in the study is complete?

Yes. You can stop being in this study at any time. Your parents can also tell us that they don't want you to be in the study. You or your parents can tell us you want to leave the study by contacting the people listed on the first page of this form.

Will you get any money for being in this part of the study?

No. We will not pay you or your parents for being in this part of the study.

Will you be charged for being in this part of the study?

No. We will not charge you or your parents for being in this part of the study.

What if you have questions about your rights as a research participant?

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 can contact the Institutional Review Board at 919-966-3113 or email them at IRB_subjects@unc.edu. The IRB reviews all studies of people to make sure they are kept safe and treated right. They make sure we follow the rules when we do this study. You do not have to use your name.

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 be in the study

______________________________________ ______________
Sign your name here if you agree to be in the study Date

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Print your name here if you agree to be in the study

______________________________________ ______________
Signature of Research Team Member Obtaining Assent Date

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Printed Name of Research Team Member