**University of North Carolina-Chapel Hill**

**Assent to Participate in a Research Study**

**Assent Form 1: Randomization to Research Genomic Sequencing**

**Adolescent Subjects age 15-17**

**Biomedical Form**

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**IRB Study #** 17-0816

**Consent Form Version Date:** **10-09-2018**

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

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**This consent form is for participants whose families have already enrolled in the first part of the NCGENES 2 study. We are inviting you to join the second part of the study.**

**What are some general things you should know about research?**

Research is done to learn new information that may help other people in the future. You *may* *not* receive any direct benefit from being in this research study. There may also be unknown risks. We are asking you to join the second part of the NCGENES research study. In this form, we will use the word “parent” to mean one or both of your parents or your guardian.

You do not have to join this study if you do not want to, even if your parent has already given their permission. It is up to you to decide to join. You can refuse to join or you can stop being in the study, for any reason. You do not have to be in this research study to get medical care.

Details are discussed below. It is important that you understand this information so that you can make an informed choice. You will be given a copy of this form. You should ask the researchers or research staff any questions you have about this research study at any time.

**Why are we doing this study?**

This part of the NCGENES study is looking at the effect of using a genetic test called “genomic sequencing.” We want to learn whether genomic sequencing can diagnose a medical condition sooner and change a child’s future medical care. We are comparing it to what happens when children get usual care. “Usual care” includes all the evaluations and tests done as part of a specialty clinic visit. Right now, genomic sequencing is not often part of usual care.

We also want to learn how families understand, talk about, and use information they get from their child’s specialty clinic visits.   
  
**How many people will take part in this study?**

We expect 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 sign a form that allows us to see information from your medical record that is needed for the study. This information includes your health history, family medical history, and some laboratory test results.

We will use “randomization” to divide the families who join this part of the study into two groups: Group 1 and Group 2. Randomization is like flipping a coin. It makes sure that every family has an equal chance of getting in one group or the other. You and your parents will be told which group you are in after you agree to being in this part of the study and sign this form.

***If you are in Group 1***:   
You will get usual care from your specialty clinic doctors. This is the same care that you would get in this clinic if you were not in the NCGENES study. The doctor will do a physical exam. You *may* also have one or more of the following:

* Additional testing, including some kinds of genetic tests
* Medical procedures, such as an MRI
* Referral to other specialists, including therapists
* Other recommendations.

These things are all part of usual care. They are not part of the NCGENES study and the study will not pay for them. However, we will track the results of these things to see if they affect your future health and medical care.

***If you are in Group 2***:   
You will get usual care from your specialty clinic doctors, as described above. You will also be offered genomic sequencing to look for a genetic reason for your condition.

You and your parents will be told which group your family is in after you consent to join this part of the study and sign the consent forms.

***If you are in Group 1***:

You do not have to do anything.

***If you are in Group 2****:*

We will give you and your parents more information about genomic sequencing. We will then ask your parents to decide whether they want you to have genomic sequencing. To agree to this testing, they will sign a separate consent form. We will ask you for your assent and if you agree, and you will be asked to sign separate assent form. You and your parents can also decide against your having genomic sequencing. These decisions will not affect your medical care.

**How long will your and your family’s part in this study last?**

Your family will be contacted about 3-6 months after your specialty clinic visit. At that time, a doctor will discuss test results from your usual care and from the research genomic sequencing, if it was done.

After the follow-up contact, we will check on your health over time, including after the study has ended, by using your medical records and other sources of information. We will stop doing these things when you turn 18 years old.

In addition, we will contact you and your parents if we learn new information during the study that would affect your medical care or your willingness to continue being in the study. We may also contact you about joining future research studies. You can accept or decline to join these studies at that time.

**What are the possible benefits to you?**

The goal of research is to benefit society by gaining new knowledge. The study will help us understand how to use genomic sequencing with patients and help us find out if that use affects a child’s future medical care or not.

**What are the possible risks involved with participating in this study?**

**Risk to Confidentiality and Privacy:** There is a small risk to your privacy and the confidentiality of the information we gather in the study. However, this study has many ways to protect your privacy and confidentiality. These include using participant ID numbers, special ways to store information, and how we share our research findings.

**Use of Participant ID Numbers:** All study materials will be coded with a unique participant ID number instead of your name or other information that can be used to identify you. We will store the records that link your ID number to your personal identifying information on a secure computer in a password-protected file with restricted access.

**Electronic information:** Information including that from your medical records will be stored on secure computers in password-protected files with restricted access.

**Paper Documents:** Paper documents will be stored in a locked filing cabinet in locked offices.

**Research Publications:** When we report results from this study, we will not identify you.

We will make every effort to keep your research records private. However, there may be times when federal or state law requires us to disclose them. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of your personal information. In some cases, the information could be reviewed by University representatives or research sponsors for purposes such as quality control or safety.

To help us protect your privacy, we have obtained a **Certificate of Confidentiality** from the National Institutes of Health. This means that we cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. We will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government if they need to audit or evaluate a federally funded project or if it is required by the Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you give an insurer, employer, or other person your written consent to receive research information, then we may not use the Certificate to withhold that information.

**Other risks to study participation**: There may be uncommon or other risks of being in this study that we currently do not know about. You should report any concerns to the researchers listed on the first page of this form.

**Who is sponsoring and paying for this research?**

This research study is being paid for by a grant from the National Human Genome Research Institute at the National Institutes of Health (NIH). We are paid to carry out the study but we do *not* have a direct financial interest with the sponsor or in the final study results.

**Data Sharing with Qualified Researchers**

By signing this consent form, you are allowing us to share information about you with researchers to study the clinical use of genomic sequencing.

* Study data that is linked to your personal information (identifiable data) will be shared among NCGENES investigators through a secure, restricted-access data system and under a contract known as a Data Use Agreement that assures privacy protections.
* Coded study data, the data that does not include your personal identifying information, may also be shared with other investigators who are not members of NCGENES but who have been approved by the NCGENES steering committee.

The NIH is the government agency that pays for most medical research in the United States. Because this study is funded by NIH, the study will share its data with NIH and other data banks. The data we share will not include any personal identifying information. By collecting the health information obtained from many research centers, the NIH and other data banks will store it so other qualified researchers can use it to do more studies. Researchers can be from a government, academic, or commercial site, and studies may be done at many places at the same time.

**Risks to Privacy and Confidentiality by Data Sharing**

We think that there are low risks to your privacy and confidentiality from sharing your health information with other databanks; however, we cannot predict how this information will be used in the future. These databases have safeguards to protect information while it is stored and used for research. If you have a genetic condition, this information will be sent with only a code number. Your personal identifying information will *not* be used.

If you no longer want your data in these databases, you can choose to withdraw your assent at any time with no penalty by contacting the researchers on the front page of this form.  However, data that has already been sent to researchers cannot be retrieved from them

**Will researchers seek approval from you to do future studies involving the samples?**

A committee called the Institutional Review Board (IRB) protects the rights and welfare of research participants in current and future research and will decide about the need for future contact. In some cases, the IRB may determine that future research using your study-related data is acceptable without re-contacting you or your parents. In other cases, the IRB may require that you and your parents be re-contacted and be asked for your consent. You have the right, at that future time, to refuse to participate. This refusal will *not* affect your medical care and it won’t cause you to lose benefits to which you are entitled.

**Optional Consent for Storing Study Data with Identifying Information After the Study Ends:**

In the future, after this study is over, researchers may identify new questions that might be answered with the use of your study data. The data from the NCGENES study will be stored in what we call a “repository” or “data bank”. The kind of data that the study will store includes information from your medical records that was used for NCGENES, or other related data. We will store this information labeled with only a code or number so that you are not identified. We will not share data that has your name or personal identifying information on it. We will keep a list that can link your identity to the code or number that is labeled on your information, but we will not share this link with anyone outside of the study team. When you turn 18 years old, we will remove the link so your information will be completely de-identified, that is no longer linkable to your identity.

It is unlikely that you will benefit from these future research studies. Futures studies that use the data from this repository or data bank may help us develop new research projects and answer new research questions. For example, future studies may provide additional information that will help us understand the different types of conditions children have, how families search for answers to the cause of their child’s health condition, how doctors communicate with families, and the types of tests and care that children who have these kinds of conditions receive throughout their lifetime.

The risks of participating in these future research studies are similar to the risks described above. Sometimes people are concerned that others may find out things about them. For example, they may be worried that someone will find out about information from a medical record. There is a low chance that others will find out about these things if the data are stored in this repository or data bank because the data will not be linked to your identity. Researchers who use these data will not know which data came from you and which came from other people in this or other studies. There will be no cost to you for the storage and use of the data for research purposes. At any time, even after the study has ended, you can decide that you want to withdraw your data from the data bank. To do so, you should contact the researcher whose name is listed on the front page of this consent form.

Do you agree to the use of your data collected for the NCGENES study in future studies after NCGENES?

\_\_\_\_\_ I agree to this use \_\_\_\_\_ I do **NOT** agree to this use

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

Yes. You can withdraw from this study at any time, or your parents can withdraw you, without penalty by contacting the researchers listed on the front page of this form.

**What if we learn new things or information during the study?**

You and your parents be given any new information gained during the study that might affect your medical care or your willingness to continue participating.

**What will happen if you are or your child is injured by this research?**

All research involves a chance that something bad might happen to participants including the risk of personal injury. UNC-Chapel Hill has *not* set aside funds to pay for any such injuries, or for the related medical care. However, by signing this form, you do *not* give up any of your legal rights.

**Will there be any cost to you for being in this research study?**

Neither you nor your parents will be charged for participating in this part of the study.

**Will you receive anything for being in this part of the study?**

We will not pay you or your parents for participating in this part of the study.

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

The IRB reviews all research on human volunteers to protect your rights and welfare. If you have questions or concerns about your rights as a research participant you may contact, the IRB at 919-966-3113 or to [IRB\_subjects@unc.edu](mailto:IRB_subjects@unc.edu). You do not have to use your name.

**Participant Agreement:**

I have read the information provided above and have asked all the questions I have at this time. I voluntarily agree to my participation 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.

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Your signature, if you agree to be in the study Date

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Your printed name. if you agree to be in the study

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Signature of Research Team Member Obtaining Assent Date

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Printed Name of Research Team Member