University of North Carolina at Chapel Hill
Assent to Participate in a Research Study
Adolescent Participants age 15-17- Relatives of a Study Subject

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Consent Form Version Date: 12-04-2014
IRB Study # 11-1865

Title of Study: NCGENES: A Next-Generation Sequencing Platform for Genetic Diagnosis and Research

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Funding Source and/or Sponsor: UNC Chapel Hill, National Human Genome Research Institute at the National Institutes of Health

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

You are being asked to take part in a research study. Your parent, or guardian, needs to give permission for you to be in this study. You do not have to be in this study if you don't want to, even if your parent has already given permission. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

Why are you being invited to participate in this study?

You have a family member who is part of a study at UNC called NCGENES. Part of this study involves genetic testing, which looks for alterations (variants) in the genes that can cause disease.

Most genetic variants are harmless, but some can cause a disease. When we do genetic testing, there are three types of results that are possible. A positive result means that a genetic variant was identified that is known to cause disease. A negative result means either no genetic variants were identified, or that only harmless variants were found. Finally, genetic testing can identify a variant of uncertain significance (VUS). A VUS result means that a genetic alteration was identified, but we do not know for sure whether it causes disease or not. Your relative had genetic testing that identified a VUS.

Sometimes testing others in the family can help us determine if a VUS is harmful or not. For example, if several members of a family with cancer all have the same VUS, while family members without cancer do not, this make us think that the VUS may be causing the disease. You are being invited to participate in this study, because your relative's genetic testing identified a VUS and knowing whether you have the same genetic variant may give us additional information that could us understand this result better.

Your participation will be limited to testing for the VUS previously identified in your relative. You are not being enrolled in the full NCGENES study.

How long will your child's part in this study last?

Your part in this study is expected to last less than an hour.

What will happen if you take part in the study?

- Participation in this study involves obtaining a blood sample from you. This blood sample can be drawn at UNC, or we can help you arrange a blood draw in your local area. One tube of blood (7ml, or 1-2 teaspoons) will be collected.
- The tube will be pre-labeled with your unique participant ID number. It will be sent to the UNC Molecular Genetics laboratory. The link between the number and your name will reside in our password protected database.
- Your specimen will be analyzed to determine whether or not you carry the genetic variant previously identified in your relative.
- When the testing is done, the laboratory will report clinically relevant results to a certified genetic counselor or medical geneticist on the research team and he or she will then report the results to your parents by phone.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. There is little chance you will benefit from being in this research study.

What are the possible risks or discomforts involved with being in this study?

This study requires a blood draw, which may cause minor bruising or bleeding.
In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will your privacy be protected?
When it arrives in the laboratory, your specimen will be labeled with a unique ID number and the link between this ID and your personal identifying information will be held in a secured database with access restricted to certain study personnel. This consent and other paper documents will be stored in a locked office.

No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. However, by signing this form, you do not give up any of your legal rights.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
You will not receive anything for taking part in this study.

Will it cost you anything to be in this study?
If you are in this study, you are responsible for the cost of travel to UNC or the location you select to have your blood draw. They study is unable to pay for mileage or parking fees.

The blood draw and genetic testing for the variant previously identified in your relative will be paid for by the study. If you have your blood draw at UNC, there will be no charge for the blood draw. If you choose to have your blood drawn elsewhere, it is possible that you will get a small bill for the blood draw (phlebotomy) fee. Once you have paid this fee, you can submit the receipt to be reimbursed by the study.

What if you are a UNC student?
You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you take part in this research.

What if you are a UNC employee?
Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

Who is sponsoring this study?
This research is funded by a grant from the National Human Genome Research Institute at the National Institutes of Health. The UNC Lineberger Comprehensive Cancer Center and the University Cancer Research Fund are supporting parts of the study. This means that the research team is being paid to carry out the study. However, the researchers do not have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research subject?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Subject's Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

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Signature of Research Subject Date

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Printed Name of Research Subject

_____ _____

Signature of Research Team Member Obtaining Consent Date

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Printed Name of Research Team Member Obtaining Consent