

**University of North Carolina-Chapel Hill  
Parental Consent for Child to Participate in a Research Study  
Minor Subjects- Relatives of Study Subject  
Biomedical Form**

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**IRB Study #11-1865**

**Consent Form Version Date:** 12/04/2014

**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 NIH

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**Study Contact telephone number:** 919-843-3349

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

Your child is being asked to take part in a research study. To join the study is voluntary. You may refuse to have your child join, or you may withdraw your consent for him or her to be in the study, for any reason.

Research studies are designed to obtain new knowledge that may help other people in the future. Your child 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 child's relationship with the researcher, his or her health care provider, or the University of North Carolina-Chapel Hill. If your child is a patient with an illness, he or she does 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 is your child being invited to participate in this study?**

Your child has 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 are harmful and can cause specific 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 variant was identified, but there is not enough information to know whether it causes a disease or not. Your child's relative's genetic testing identified a VUS.

Sometimes additional testing in family members 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 provides more evidence that the VUS may cause disease. Your child is being invited to participate in this study, because his or her relative's genetic testing identified a VUS and knowing whether your child has the same genetic variant may give us additional information that could improve our interpretation of this result.

Your child's participation will be limited to testing for the VUS previously identified in his or her relative. Your child is not being enrolled in the full NCGENES study.

### **How long will your part in this study last?**

Your child's 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 your child. 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 a unique participant ID number. It will be sent to the UNC Molecular Genetics laboratory. The link between the number and your child's name will reside in our password protected database.
- Your child's specimen will be analyzed to determine whether or not he or she carries the genetic variant previously identified in the 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 you 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 your child 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 allow your child to continue participating.

**How will your privacy be protected?**

When it arrives in the laboratory, your child's specimen will be labeled with a unique ID number and the link between this ID and any 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 participants 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 child's 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 your child. This may include the risk of personal injury. In spite of all safety measures, your child might develop a reaction or injury from being in this study. If such problems occur, the researchers will help your child 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 your child from this study at any time, without penalty. The investigators also have the right to stop your child's participation at any time. This could be because he or she has 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?**

Neither you nor your child will receive anything for taking part in this study.

**Will it cost you anything to be in this study?**

If your child is in this study, you are responsible for the cost of travel to UNC or the location you select to have the blood drawn. The 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 your child has blood draw at UNC, there will be no charge for the blood draw. If you choose to have your child's blood drawn elsewhere, you may get a small bill for the blood draw fee. After paying this fee, you can send us the receipt to be reimbursed.

**What if you are a UNC student?**

You may choose not to have your child participate in the study or to stop him or her from 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?**

Agreeing to have your child take 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 child’s 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 allow my child to participate in this research study.

\_\_\_\_\_  
Signature of Research Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Research Subject

\_\_\_\_\_  
Signature of Research Team Member Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Research Team Member Obtaining Consent