

**Introducing the NCGENES 2 Research Study**

We are inviting you to join a research study called the North Carolina Clinical Genomic Evaluation by Next-gen Exome Sequencing. We call it **NCGENES.**

**Who is being invited to join NCGENES?**We are inviting families of children who have a doctor’s appointment at a pediatric specialty clinic to try to find out if there is a genetic cause to their condition. This research study is ***not*** part of your child’s specialty clinic appointment. Even if you do not wish to join the study you should still attend your child’s appointment for their evaluation and ongoing medical care.  **What is the NCGENES study about?**

**There are 2 steps to the NCGENES study.**

**The first step of the study:**

In this part of the study, we are trying to find ways to help families understand more about what to expect from going to their child’s specialty clinic visit. We also want to find ways to help families feel more comfortable talking to their child’s specialty doctors.

**The second step of the study:**

After your child’s specialty clinic visit, you will be invited to join the second part of the study. You can join or decline to join at that time. In the second part of the study, we will look at the effect of using a genetic test called “genomic sequencing.” We want to learn whether this test can find a genetic cause of a child’s medical condition faster than other tests. We also want to find out if having this test changes the child’s future medical care.

**What will you be asked to do if you join the first part of the study?**

Everyone who joins will do the following things:

* + fill out a questionnaire before your child’s appointment with the specialty clinic
  + answer 2 surveys roughly 6 and 12 months after that visit

We will pay you $120 for finishing all of the surveys.

We will divide the families who join the study into 2 groups in a way that is like flipping a coin. This is called “randomization”. Each family has the same chance of getting in one group or the other.

**If you are in Group 1:**

We will mail you a brochure called “***What to expect at your child’s specialty clinic appointment.***” It will include a list of questions that you may want to ask your child’s specialty clinic doctor during the visit. We will ask that you read the brochure and decide which questions you want to ask at the visit.

If your child comes back for a second visit, you will be sent a second brochure that describes that visit and includes other questions to ask. We will ask you to read that brochure and decide which questions you want to ask at that visit.

**If you are in Group 2:**

You will not be sent these brochures about your child’s specialty clinic appointment.

**What are the possible benefits to you if you join this part of the NCGENES study?**

You and your child may not directly benefit from being in the study.

If you join the first part of the study, it may teach us how to help families like yours to understand more about what to expect at their child’s specialty clinic visit. It may also show us how to help them become more comfortable talking to their child’s specialty doctors.

**What are the possible risks to you if you join this part of the NCGENES study?**

The risks for being in this part of the study are like those that anyone has in a normal day of life.   
 **What are other things to know about the study?**  
You will ***not*** be charged for any of the activities in the NCGENES study. If you don’t want to join, it will ***not*** affect your child’s medical care or the costs of care.

**What will happen next?**

Someone from the research team will call you to see if you are interested in joining the first part of the study and to tell you more. You can join or decline to join at that time.

**If you decide to join the NCGNES study:**

We will mail you a questionnaire and a pre-paid self-addressed envelope. **Before your child’s appointment**, you should complete this questionnaire and use the envelope to return it to the NCGENES study.

**If you decide not to join the study:**

Deciding not to join the study is OK. It will ***not*** affect your child’s specialty clinic appointment.

***Participating in this research study is separate from your child’s specialty clinic visit.***

***Even if you decide not to join the study, it is very important that you still attend your child’s scheduled appointment with the specialty clinic.***

Thank you for your interest in the NCGENES Research Study.

Please contact a member of our research team if you have any questions:

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