

Seattle Children's  
Seattle, Washington  
Institutional Review Board

04/15/14

**APPROVED**

- **Assent Form for children 7 to 13 years of age**

Parent/legal guardian signature required for participants under 18 years of age.

## Genotype-phenotype analysis of chromosome disorders

### Researchers:

<u>Name</u>	<u>Position</u>	<u>Department/Division</u>	<u>Telephone</u>
Heather Mefford	Principal Investigator	Pediatrics/Genetic Medicine	206-543-9572
Margaret Adam	Attending Physician	Pediatrics/Genetic Medicine	206-987-2689
Ian Glass	Attending Physician	Pediatrics/Genetic Medicine	206-987-5142
Mark Hannibal	Attending Physician	Pediatrics/Genetic Medicine	206-987-1389
Dan Doherty	Attending Physician	Pediatrics/Genetic Medicine	206-987-2590

You can call Dr. Mefford at 206-543-9572 (office) or 206-919-1723 (cell phone) or 206-469-2926 (pager). You can also call Seattle Children's at 206-987-2000 and ask to talk to the Genetics doctor on call. Please ask your parent or an adult if you need help.



### What is a research study?

Research studies help us learn new things. We can test new ideas. First, we ask a question. Then we try to find the answer. This study can help us learn about how changes in our chromosomes, or "instruction manuals" for our bodies cause some of us to look or act or learn differently.

This paper talks about our research study. We want you to ask us any questions that you have. You can ask questions any time.

There are a few things you should know about the study:

- You get to decide if you want to be in the study.
- You can say 'No' or you can say 'Yes'.
- Whatever you decide is OK.
- If you say 'Yes', you can always say 'No' later.
- No one will be upset if you say 'No'.
- We will still take care of you no matter what you decide.



### **Why are we doing this research study?**

We want to talk to you about this study because you have a small change in one or more of your chromosomes. Chromosomes are small packages in all of our cells that carry the “instructions” for building our body. Half of our chromosomes come from our mom, and half come from our dad. Sometimes those packages have holes in them, which means some of the instructions are missing. Sometimes the packages have extra sets of instructions.

In this study we want to find out more about how difference in chromosomes can cause some people to look or act or learn in a different way than other people.



### **What would happen if I join this study?**

If you decide to be in the study, you would visit a genetics doctor one time. The research doctor would ask questions about how healthy you and the other people in your family are. We would also ask if we can take your picture for the study. Finally, we will ask for a blood sample. This will let us study your chromosomes.



### **Could bad things happen if I join this study?**

The researcher would need to test some of your blood. These pokes can hurt. Sometimes the needle can leave a bruise on the skin. We can put a cream on your skin before we take blood. This cream would help so it won't hurt as much.



**If I join the study would it help me?**

We do not think being in this study would help you.

We hope to learn something from this study. And someday we hope it will help other kids who have chromosome changes like you do.



**What else should I know about this research study?**

Being in the study is your choice. You can say 'Yes' or 'No'. Either way is OK. It is also OK to say yes and change your mind later. You can stop being in the research at any time. If you want to stop, please tell the research doctors.

Sometimes we do research with other doctors and researchers. We might tell them about your chromosomes change. We will not tell them your name or where you live.



**Can I do something else instead?**

If you don't want to be in the study, you don't have to be.



**Would I be paid if I do the study?**

No, you would not be paid.



**If I have questions who do I ask?**

You can talk to Dr. Mefford. Ask us any questions you have. You can ask questions any time. Take the time you need to make your choice.

**Child's/Adolescent's Statement**

The researchers have told me about the research. I had a chance to ask questions. I know I can ask questions any time. I want to be in the research.

I know that being in the research is up to me. No one will be upset if I don't sign this paper or if I change my mind later.

***Printed Name of Child/Adolescent*** \_\_\_\_\_

***Signature of Child/Adolescent*** \_\_\_\_\_

\_\_\_\_\_  
***Date***

**Printed Name of Researcher** \_\_\_\_\_

**Signature of Researcher** \_\_\_\_\_

\_\_\_\_\_  
***Date***

\_\_\_\_\_  
***Time***

**Original form to:**  
Research Team File

**Copies to:**  
Participant  
Parents/Guardians

**Permission to Use, Create and Share Health Information for Research**  
**Research Study Title: Genotype-phenotype analysis of novel genomic disorders**  
**IRB Study #: 13325**

The federal Privacy Rule protects your/your child's health information. The Privacy Rule is part of the Health Insurance Portability and Accountability Act (HIPAA).

If you/your child agree to take part in this research study (named above), the researchers may use, create or share your/your child's health information as part of the research. The researchers will do so **only** if you give permission to use, create or share your/your child's health information as part of the research. This form gives you information to help you decide if you will give such permission. **Please read this form carefully.** After reading this form, you can refuse to sign this form.

**What does "health information" include? It includes:**

- |                                                                                               |                                                                                  |                                                                    |                                                                  |                                                             |
|-----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|--------------------------------------------------------------------|------------------------------------------------------------------|-------------------------------------------------------------|
| <input checked="" type="checkbox"/> Name                                                      | <input type="checkbox"/> Address                                                 | <input type="checkbox"/> Social Security Number                    | <input checked="" type="checkbox"/> Medical and/or birth history | <input checked="" type="checkbox"/> Demographic information |
| <input checked="" type="checkbox"/> Results of physical exams                                 | <input checked="" type="checkbox"/> Results of laboratory and/or radiology tests |                                                                    |                                                                  |                                                             |
| <input type="checkbox"/> Interview and/or focus group data                                    | <input type="checkbox"/> Survey and/or questionnaire data                        |                                                                    |                                                                  |                                                             |
| <input type="checkbox"/> Results of behavioral tests                                          | <input checked="" type="checkbox"/> Information related to your health condition |                                                                    |                                                                  |                                                             |
| <input checked="" type="checkbox"/> Information in your medical record relevant to this study |                                                                                  | <input checked="" type="checkbox"/> Other (please specify) * _____ |                                                                  |                                                             |

\* If using a translated HIPAA Form, this information must also be translated

**What the researchers may do with health information**

Researchers may create new health information about you/your child during the study. Researchers may use health information in your/your child's records.

Researchers may also share health information about you/your child collected during the study with the following:

1. The sponsor of this study and its representatives. Sponsor Name: N/A
2. Researchers at other centers taking part in this research study.  
Name(s) of other center(s): N/A
3. Government agencies, ethics review boards, data and safety monitoring boards, and others responsible for watching over the safety, effectiveness, and conduct of the research.
4. Your health care insurance company if it is paying for care provided as part of the research study.
5. Other health care providers involved in your/your child's care.
6. National Institutes of Health and its grantholders for the purpose of research administrative activities (e.g., tracking overall research activity).

7. Others, as provided by law.

**The Privacy Rule applies to doctors, hospitals and other health care providers.** Some of the groups listed above are not required to follow the Privacy Rule and may share your/your child's information with others, if other laws allow. However, other privacy protections may still apply.

### **Research Records**

You may look at or copy the information that may be used or disclosed. However, for certain types of research studies, some of the research records may not be available to you/your child while the study is going on. This does not affect your right to see what is in your/your child's medical (hospital) records.

The researchers may publish or present the research findings. You/your child will not be identified in any findings that are published or presented.

The federal Privacy Rule does not apply to health information that is not identified in any way. The researchers may decide to remove any information that could identify you/your child. If they do this, the information may be used and shared by the researchers and the sponsor as the law allows. This may include use in other research studies.

### **Permissions to Take Part in Research**

If you agree to take part or allow your child to take part in the research, you will be asked to sign a **research consent form**. The research consent form gives you details about the research. The consent form describes the risks and benefits of the research. It explains the purpose of the study, what will happen and other important information for you to know.

**To be in this research study, you must also sign this permission form** (Permission to Use, Create and Share Health Information for Research). If you do not want to sign this permission form, this will not affect the care and treatment you or your child receive.

### **How Long does the Permission Last? What if You Change Your Mind?**

- ☐ This permission is valid until the end of the research study;
- or
- ☒ This permission will not expire, because this is a research database or repository study (i.e. specimens and/or data are stored permanently).

Except for the research database and repository studies, your/your child's information will be destroyed or any personal identification will be removed at the end of the research study. If you change your mind and want to cancel your permission, please let us know in writing. Write to Principal Investigator (PI)/Researcher:

**Heather C. Mefford, MD, PhD**  
**University of Washington, Dept. of Pediatrics**  
**1959 NE Pacific St., Box 356320**  
**Seattle, WA 98195**  
**Email: DNASTudy@uw.edu**

**If you cancel your permission and you/your child are a patient at Children's, please send a copy of your letter to:**

Director of Health Information and Privacy, Health Information Management, A-4902, Seattle Children's, 4800 Sand Point Way NE, Seattle, WA 98105-0371.

If you cancel your permission, no other health information about you/your child will be collected for this research. However, the health information that was received with your permission may be shared or used. For example, researchers may need to use or share this information:

- for safety reasons;
- to verify the research data;
- if required by law.

If you agree to take part or allow your child to take part, you will be given a copy of this permission form after you have signed it.

### **Permission**

I agree to the use, creation, and sharing of my or my child's health information for purposes of this research study (named on page 1). For Children's patients, your medical record # will be recorded on this form and used to place a copy of this form in your medical record.

<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Printed Name of Participant	<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Signature of Participant (if 18 years or Older)
<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Date	<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Time
<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Printed Name of Participant's Parent or Legal Representative	<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Signature of Research Participant's Parent or Legal Representative (if younger than 18 years)
<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Date	<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Time

### **Researcher Obtaining Authorization**

<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Printed Name of Research Team Member*	<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Signature of Research Team Member
<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Date	<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> Time

**\*INSTRUCTIONS TO RESEARCHER**

1. File signed original of this form in Research File ☐
2. Provide copy of signed form to Research Participant/Parent ☐

**For Children's Patients**

3. Complete or attach patient label: ☐

Participant's Medical Record # \_\_\_\_\_

Participant's Date of Birth      \_\_\_\_/\_\_\_\_/\_\_\_\_

4. Send copy of the signed form to Health Information Filing: Mailstop A-4902 ☐