

**Children's Hospital & Regional Medical Center
and
University of Washington**

Children's Hospital and Regional Medical Center
Seattle, Washington
Institutional Review Board

Seattle, Washington

JAN 02 2008

**Consent Form
for
Parents, Guardians, and Participants 14 Years of Age and Older**

APPROVED

**FORM A
Genetic Analysis of Congenital Heart Defects**

Researchers:

<u>Name</u>	<u>Position</u>	<u>Department/Division</u>	<u>Telephone</u>
Mike Bamshad	Principal Investigator	Pediatrics/Genetics&Development	206-221-4131
Maggie McMillin	Study Coordinator		206-221-3849

24-hour emergency telephone contact: The principal investigator can be reached during work hours at (206) 221-4131 or 801-232-0579 (cell phone) or 206-469-2280 (pager). If not immediately available please page the Genetics Pediatrician on call by calling (206) 987-2131.

Researchers' Statement

Introduction

You are being asked to take part or to allow your child to take part in a research study. Taking part in research is voluntary. Please take time to make your decision, and discuss it with family and friends.

This form provides a summary of the information the researchers will discuss with you. If your child takes part in this research study, you will keep a copy of this form. Be sure to ask any questions you have about the research study.

You/your child are being asked to take part in a research study because you/your child have a birth defect of the heart, sometimes called heart defect.

Why is this research study being done?

The purpose of this research study is to improve our understanding of the causes of heart defects. Specifically, we are trying to find genes that influence whether or not a person is born with a heart defect. We would also like to know why the same change in a gene(s) sometimes causes different problems in different people.

Even though we understand how some heart defects are inherited and we have begun to understand what changes lead to heart defects, we do not understand how changes in genes influence most heart defects. In our laboratory we will compare genes from individuals with heart defects to those without heart defects. If we can begin to understand how changes in genes influence heart defects, we may be able to develop improved treatments. This research could even be important in the development of methods of preventing heart defects.

Are there benefits to taking part in the study?

Taking part in this research study will be of no direct benefit to you or your child.

You/your child will **not** get specific information back from this study about the gene defect in your family.

How many people will take part in the study?

We hope to enroll people in this project continually for the next five years. We plan to include approximately 900 individuals in the entire study. Participants will be recruited locally and nationally.

What is involved in the study?

We will give you/your child a physical examination. We will collect about 1 to 3 teaspoons of blood one time. We may ask to collect some skin cells from the inside of your/your child's cheek with a soft swab. We will review your/your child's medical record and collect information about health and about the results of tests, such as x-ray tests done for medical care.

We **may** ask to take pictures of your/your child's heart. This is called an ultrasound image. Ultrasound uses sound waves to make images of organs in the body. You/your child will be awake during the ultrasound. A transducer is placed on the outside of the skin with a jelly to help the image.

We **may** ask to measure the electrical activity of your/your child's heart. This test is called an echocardiogram and it is painless.

We **may** also ask to take a picture called a chest x-ray. This will not cause pain.

You/your child can choose **not** to have an ultrasound, an echocardiogram, and a chest x-ray. You/your child can still be in this research study if you/your child decide not to let us do the ultrasound, echocardiogram, or the chest x-ray.

We will study the genetic material called DNA that is collected from the blood or tissue cells. We may try to grow some of your/your child's white blood cells in our laboratory. If the white cells grow, we will use them as a source of DNA to study in the future. Blood cells that are grown in the laboratory are called cell lines.

If gene mutations (changes) that may have caused your/your child's heart defect are identified, we will tell you/your child about these mutations. You/your may choose to have this research information confirmed in a clinical laboratory. This testing is not part of this research study and will be billed to you or your/your child's insurance company. The research doctor will tell you/your child about this testing.

How long will I/my child be in the study?

You/your child will be in the study for one clinic visit and for 15 years after the visit. The clinic visit will last between 1 and 3 hours. We may contact you after the clinic visit, via phone or through your doctor, to ask some questions about the development of you/your child's condition. For example we may ask about, physical developments, surgical procedures or other therapeutic interventions you/your child has had.

You/your child can decide to stop taking part in this study at any time.

What are the risks of taking part in this research study?

Drawing blood may cause slight discomfort or pain. A small bruise may form. You/your child may feel light headed. We will make every attempt to take the blood sample at the same time you/your child are having blood taken as part of medical care. We will try to make you/your child comfortable during the blood draw.

There are no known risks associated with use of the cheek swab to collect cells.

An echocardiogram is an ultrasound examination of the heart. This is the same technology that is used to look at a fetus during a pregnancy.

X-rays involve small quantities of radiation. The largest amount of radiation that would be involved in these studies is about the same as the maximum yearly exposure considered acceptable for the workplace. If we request that your child have any X-rays taken we will explain the reasons and give you more information about the exact amounts of radiation involved.

If a gene mutation is identified in this study, you/your child may choose to send another blood or tissue sample to a clinical laboratory for testing. It is possible that there will be no certified clinical lab able to test for certain mutations causing heart defects.

Be sure to ask the research doctors any questions you have about taking part in this research.

What other options are there?

You/your child may choose **not** to take part in this research study and still receive medical care for your/your child's heart defect.

What about confidentiality?

Your/your child's participation in this study and the information we gather about you/your child will be confidential. Code numbers will be used to identify tissue samples and information. Research results will **not** be entered in your/your child's medical record. Any publication resulting from this study will not reveal your/your child's identity. The samples, genes, and cell lines will not be used for any other research projects without your permission. If you/your child asks to withdraw from the study, your/your child's samples will be destroyed, and all the research information that identifies you/your child will be destroyed. Research results will be the property of the Bamshad laboratory at the University of Washington.

Our laboratory will keep research records that contain identifiable information. The identifiable information will be stored separately from the research information (data). This information includes a medical record number, names, and contact information. This information is kept in a locked file. Only researchers listed on this form will view this information. The research doctor controls the access to this information. You/your child may choose to withdraw from the study and ask us to destroy this identifiable information. Please talk to Dr. Bamshad if you/your child want to withdraw from the study and have the information that can identify you/your child destroyed.

What are the costs of the research study?

Neither you nor your/your child's insurance company will be charged for taking part in this study. There will be no cost for any research procedure or exams, including the blood draw, cheek swab, radiographic procedures, and lab tests.

If you or your child is injured as the direct result of taking part in this research study, we (Children's Hospital and Regional Medical Center) will treat you or your child. If appropriate, we will refer you or your child for treatment. The University of Washington will pay for the cost of this treatment within the limits of its compensation program. No other form of compensation is available. Please call Michael Bamshad, MD at 206-221-4131 if you believe you or your child has been injured as a result of this study.

Will my child or I be paid to take part in the study?

You/your child will not be paid to take part in this study.

What are my rights and my child's rights as a research participant?

Taking part in research is voluntary. You may decide not to take part or not to allow your child to take part. If you/your child do take part, you/your child may withdraw from the study at any time. Your decision will not affect your/your child's medical care at Children's Hospital & Regional Medical Center. There are no penalties or loss of benefits if you choose not to take part or have your child take part or to withdraw early.

Whom do I call if I have questions or problems?

If you have any questions about the study please call the study coordinator Maggie McMillin at 206-221-3849 or Michael Bamshad, MD at 206-221-4131.

In the event of an emergency or for possible research related injuries call Michael Bamshad, MD at 801-232-0579 (cell phone) or 206-469-2280 (pager). If not immediately available please page the Genetics Pediatrician on call by calling (206) 987-2131.

For questions about your child's rights as a research study participant, contact the Children's Hospital and Regional Medical Center Institutional Review Board (IRB). The IRB is responsible for protecting the rights of children and families taking part in research. They may be reached at (206) 987-2023.

Signature of Researcher Obtaining Consent

Date

Parent's Statement

The research study described above has been explained to me. I voluntarily agree to take part or to allow my child to take part in this research study. I have had the chance to ask questions. I understand that the persons listed above will answer any future questions I have about the study or about research participants' rights.

May the researchers contact you in the future to ask more questions about you/your child's condition being studied in this research?

"Yes" The researchers have my permission to contact me in the future regarding my/my child's condition being studied in this research.

"No" The researchers may NOT contact me in the future regarding my/my child's condition being studied in this research.

Name of Child

Signature of Participant

Date

Signature of Parent or Legal Guardian

Date

Signature of Witness (if interpreted)

Date

Copies to: Parents
 Researchers' file