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

Seattle, Washington

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

FORM B
Genetic Analysis of Congenital Heart Defects

Researchers:

Name	Position	Department/Division	Telephone
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 family member with 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, your child, or family members with heart defects.

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?
For your/your child's participation, 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 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 family member's heart defect are identified, we will tell your family member about these mutations.

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.

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.

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. This will not affect the regular medical care of any of your family members involved in the study.

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, 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.

_____
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

Children's
Hospital & Regional Medical Center

Permission to Use, Create and Share Health Information for Research
Research Study Title: Genetic Analysis Heart Defects

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**.

What does "health information" include? It includes:

1. Information about you/your child that is collected during the research study. This might include the results of tests or exams that are done as part of the research. It might include surveys, diaries or questionnaires you fill out during the study. It might include answers to interviews you do as part of the research study.
2. Information that is in your/your child's medical records that is needed for the research study. These might include the results of exams, blood tests or x-rays. It might include the results of procedures done to diagnose or treat you/your child.

What the researchers may do with health information

Researchers may create new health information about you/your child during the study (see point 1. above). Researchers may use health information in your/your child's records (see point 2., above).

Researchers may also need to 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: **Centers for Disease Control and Prevention (CDC)**
2. Researchers at other centers taking part in this research study.
   Name of other centers: **University of Washington**
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 they are paying for care provided as part of the research study.
5. Other health care providers involved in your/your child's care.
6. 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

During the research, 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 **__02/_02/_2022**, unless you change your mind. On or before this date, your/your child's information will be destroyed or any personal identification will be removed. If you change your mind and want to cancel your permission, please let us know in writing. Write to Principal Investigator/Researcher:

[Provide Name and Address of PI]. **Michael Bamshad, MD**
University of Washington
School of Medicine Box 356320
1959 NE Pacific Street HSB RR349
Seattle, WA 98195-6320

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, Childrens' Hospital and Regional Medical Center, 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).

_____
Printed Name of Research Participant

_____
Signature of Research Participant (if participant is 18 years or older) Date

_____
Signature of Participant's Parent or Legal Guardian (if participant is under 18 years of age) Date

Signed original of this form must be filed in: **Researchers' file**

Copies of signed form provided to: **Research Participant/Parent**
And, if participant is Children's patient: **Children's Medical Record**

For Children's Patients Only: Researcher must send copy of signed permission form to Health Information Filing – Mailstop A-4902. Provide the information below to assist Health Information in filing a copy of this signed permission form in the participant's medical record:

Participant's Children's Medical Record Number: _____

Participant's Date of Birth: _____/_____/_____

IRB Application No.: 06-0701-02