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