



## PEDIATRIC CARDIAC GENOMICS CONSORTIUM

### CONGENITAL HEART DISEASE GENETIC NETWORK STUDY (CHD GENES)

*(Insert site Information as required)*

#### ASSENT FOR CHILD FAMILY MEMBER

You are being asked to be a part of a research study for kids with heart problems.

##### **What is this study about?**

You have a heart defect. Doctors don't know why, but would like to learn more from you and other kids and adults including your parents and even some of your family.

A group of doctors have come together to collect information and some samples so they can try to better figure out what causes heart defects and what things might affect people's health over time. Also, this study may help doctors to find new tests to find people with heart problems.

There will be many hundreds of people from all around the United States in this research study. The research will go on for a few years.

##### **What will happen in this study?**

1. Interview  
You will be asked questions like: your age and ethnicity; medical history, including heart history and lifestyle; and a family history of blood relatives such as parents, brothers, sisters and others.
2. Blood for use in this research  
About 1 tablespoon will be taken for research.
3. Saliva (Spit): Some people in the study will not be able to give blood. For those people, a saliva sample will be collected.
4. If you are having atrial septal heart surgery, the study would like to have a very small piece of heart tissue.
  - a. For other heart surgery, there is often tissue that is taken out and not used. When available, a small piece of that tissue will be taken for this study
5. Echocardiogram and/or ECG: You may be asked to have one or both tests done. An echocardiogram is a painless test using sound waves to look at the heart. You will need to lie quietly on a table for about 30 minutes while the test is being done. An ECG is a painless test. It takes about 5 minutes and looks at the heart by using stickers put on the chest and connecting the stickers to the machine to read the results.

6. The study doctor/staff may call you up later in the study and ask how you are doing and how your health has been since the last time you met.

### **Will being in the study hurt?**

- Blood draws may cause a small pinch, bruising, or even dizziness or fainting. There is also a very small risk of getting an infection because of the needle stick.
- Giving information about yourself and your family may make you nervous. If this happens, let the study person know so you can talk about your feelings. The questions can be stopped at any time.
- Spitting in a cup is painless.
- Echocardiogram and ECG are painless.
- Genetic Testing will be done on the blood. There is no direct pain when the blood is tested. The test findings will be put into the study research database and will not go to anyone other than the research team. The results will be added to the database with a super number, not anyone's name. No names will be in the database.
- If you are having an atrial repair surgery and are donating a sample, there is a very small risk of adding time to that surgery. If you are having other heart surgery, there is no risk to collecting tissue that is unused.

There may be unknown risks to being in this study, and they may develop during the study or after when the information is being looked at.

### **What do I get out of being in the study?**

There are no direct advantages to being in the study. However, your information along with all the others may someday help kids and adults who have heart problems.

### **Will it cost me anything to be in this study?**

There is no cost for being in the study.

### **Will I get any money for being in this study?**

No

Or

You will get \$\$\$ for (Insert site-specific language).

### **What happens if I'm hurt because of the study?**

Tell the study doctor team member immediately if you think you have been hurt while in the study. Emergency medical care may be available. Money for pain, expenses, lost wages and other problems caused by an injury is not available. The NHLBI/NIH will not pay the bills for the care. (Insert site-specific language)

### **HIPAA and or SITE HIV POLICY LANGUAGE**

(Insert site-specific language)

**How will my information be kept private?**

Information collected and test results for the study will not be put in your medical record.

Your information will be stored using a number and shared only with researchers who are studying heart defects.

To help protect your privacy, we have obtained a Certificate of Confidentiality from the government that says we don't have to tell other people what you tell us, even if a judge asks us. However, you should know if you tell us that you or someone else may be in serious harm, we will take steps to get help, including notifying authorities.

**Can I be taken out or ask to be taken out of the study?**

You may be taken out of the study at any time if the study doctor thinks it is better, if you can't finish the study, or if the study is stopped.

**What other things should I know?**

- Being in this study is up to you and your parents. You are free to drop out at any time. If you drop out of the study, the information already in the database will stay.
- If you want your blood taken out of the study and thrown away, this needs to be shared with the study doctor in writing. Your samples will be destroyed once the study doctor has the letter.
- The study will be explained to you. It is important you understand what you need to do. Ask questions. If you want to be in the study you will be asked to sign the end of the form.
- This study has no treatment. So, your choices are to be in the study or not.

The National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) is sponsoring this research.

**Who do you call if you have questions about this study?**

If you have questions about this study or if you get hurt, call Dr. \_\_\_\_\_ at *(Telephone Number)*. If you have questions about your rights call *(Insert the name and title of the appropriate country/site-specific person)* at *(Insert the number)*, or if you prefer, direct your questions to the following address: *(Insert address of IRB patient representative here)*.

**CHILD FAMILY MEMBER ASSENT**  
**(Use separate page for each person)**

I have explained this research study and the procedures involved in terms that he/she could understand.

\_\_\_\_\_  
Person Obtaining Assent

\_\_\_\_\_  
Signature of Person Obtaining Assent

\_\_\_\_\_  
Date

This study has been explained to me and I agree to take part in the study.

\_\_\_\_\_  
Name of Subject

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

Sibling       Other Relative

Specify: \_\_\_\_\_

**WAIVER OF CHILD FAMILY MEMBER ASSENT**

In my opinion, this child is not capable of assent.

\_\_\_\_\_  
Person Obtaining Assent

\_\_\_\_\_  
Signature of Person Obtaining Assent

\_\_\_\_\_  
Date