



PEDIATRIC CARDIAC GENOMICS CONSORTIUM

CONGENITAL HEART DISEASE GENETIC NETWORK STUDY (CHD GENES)

(Insert site information as required)

ASSENT FOR PARTICIPANT/CHILD

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?

If you agree to be in this study, you will be asked about:

- You, your health and your families' health.
- A blood sample will be taken when you are having a regular blood test or surgery. Or, you will be asked to come in for a research blood draw. 1 tablespoon will be taken. If for any reason the sample taken is not enough, you will be asked to come back for another blood test visit.
- Some people will not be able to give blood, so they will be asked for some spit in a special cup.
- If you are having atrial septal heart surgery, the study would like to have a very small piece of heart tissue.
 - 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.
- We may ask a special type of doctor, called a clinical geneticist, to briefly evaluate you. We may also ask to take a few pictures of your face for a geneticist to evaluate later. We will ask for specific permission to take these pictures at the end of this form. You can refuse to have pictures taken and still participate in the rest of the study.

- 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.

Your mom and dad may be in the study too. They will share information about themselves and their families and will be asked for blood too. Although the study would like to have kids and parents, if your parents don't want to be in the study, you can be in the study alone.

Other family, such as grandparents, sisters, brothers and cousins may be of interest to the study doctors. When the study doctor feels information from these other family members would be of use, you will be asked if it is OK to contact them. They may be asked to be in the study, give samples, and even have other heart testing done.

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. If you are already giving blood or having surgery, taking a little extra blood at that time has no effect on you or your health.
- 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.
- There are no risks to having the genetics exam, but the exam may discover new medical conditions that were not known. Your identity can be revealed by a photograph. The photographs will be kept in a secured location and will only be shared with the study researchers. If the researchers want to use the photographs in a presentation or publication, the researchers will obtain special permission from you.
- 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 takes 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 and your parents will be asked to sign at 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)*.

ASSENT TO TAKE PART IN THIS RESEARCH STUDY

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

WAIVER OF CHILD ASSENT

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

Person Obtaining Assent

Signature of Person Obtaining Assent

Date

The investigator may want to collect an atrial septal tissue sample. By initialing the line below you are giving permission for the study doctor to collect a sample when you have an atrial septal repair.

_____ (initials) A tissue sample may be obtained at the time of surgery.

The investigator may want to take photographs of you. By initialing the line below you are giving permission to the study doctor to take photographs of you. I understand that the researchers will contact me for permission if they wish to use the photographs in a publication or presentation.

_____ (initials) Photographs may be taken.