Assent Form to Participate in a Research Study

STUDY TITLE: Genomic Basis of Neurodevelopmental and Brain Outcomes in Congenital Heart Disease

_____
Name of Principal Investigator (study doctor)

_____
Telephone Number

INTRODUCTION

We want to tell you about a research study we are doing with kids and adults with heart problems. A research study is a way to learn more about something. The study doctors would like to learn more about what causes heart problems (also called CHD, or Congenital Heart Disease) and how CHD affects learning and development. CHD is when a heart problem is present at birth. The researchers will also study your genes to see how genes affect CHD. Genes are in everyone, and they determine how we look, how our bodies work, and how our bodies respond to disease. You and other kids and adults are being asked to join the study because you have CHD and because you previously took part in another study where the doctors took some blood or saliva (spit) to look at your genes.

WHAT WILL HAPPEN IN THE STUDY?

If you agree to be in this study, we will use the genetic results from the other study (the results from testing your blood or saliva (spit) to look at certain genes). If you qualify and decide you want to be in this study, you will come to one or two times for a study visit over the next 6 months. At the visit(s), the following things will happen.

You will be asked to answer some questions/testing about your health, how you are feeling, and how well you organize and understand things. The questions will last about 3 ½ to 4 ½ hours. We will give you a break if you need a break in between testing sections. We will ask your mom or dad or guardian and a teacher to answer some questions about you. We will also get some information from your medical chart and will measure how tall you are and how much you weigh.

We will also ask you to have a Magnetic Resonance Image (MRI) scan of your brain. The MRI might be done on the same day as the questions/testing or it might be done on a different day.

- The MRI scan will take about 1 hour.
- The MRI is a way to take pictures of your body. For this study, we will take MRI pictures of your brain.
- The MRI machine uses radio waves and a powerful magnet and a computer to make the pictures. The MRI machine has a circle shaped opening in the middle (like a tunnel). You will lay on a narrow table that will move into the MRI opening.

- The MRI machine will not touch or hurt you. To help take the MRI pictures, a special device like a hat, cap, or helmet will be placed over your head. This is called a coil. It will not hurt you.
- MRI machines make some loud noises like knocking, buzzing, and chirping. These sounds are normal, but we will give you headphones to make it not so noisy.
- You will need to lay very still while the MRI pictures are being taken. You may need to lie still many times for 3-8 minutes each time.
- The person doing the MRI scan will talk to you through a microphone and will tell you when to lie still and when to expect the noises.
- It will be okay for your parent or guardian to be in the MRI room with you.
- Because the MRI uses a very powerful magnet, you cannot have certain types of metal on you. The person doing the MRI will ask you some questions before you go into the MRI room to make sure you do not have any types of metal that aren't allowed.
- We do not want to do the MRI if you are pregnant. If you are a girl that is able to become pregnant, we will test some of your urine (pee) or blood to find out if you are pregnant. The result of the test results will/will not _____(per institutional policy) be shared with your parent or guardian.

If any of the assessments or the MRI images are found to be incomplete, we may ask you to come back for repeat testing. The need to redo the testing is not likely and will only be done if you and your parent/guardian agree for you to have the tests repeated.

We may also call your parents or guardian once a year (for up to 5 years) after you are finished with the study to see how you are doing.

After the study is over, we will keep your information from the study and will store it using only a number and not your name. We may share the information (but not your name) with researchers studying heart disease and other diseases.

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

We do not know if being in this study will help you. We may learn something that will help other children with CHD someday. The study may help the doctors understand CHD better or may help the doctors find new ways to help people with heart problems in the future.

WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

The questions that are asked as part of this study might make you feel uncomfortable or frustrated. There might be some questions you can't answer. Most kids will have questions that they do not know how to answer. That is okay. Tell us if you do not want to answer some questions. If you are feeling sad or nervous about the questions, let us know and we can have someone talk to you about what you are feeling. The questions might take a long time and can be boring. Tell us if you need to take a break.

The MRI scan does not touch or hurt you. It might make you uncomfortable to lie still or to lie in

the small space. Also the MRI is noisy. The person doing the MRI will give you earphones to make it less noisy. He or she will also try to make you as comfortable as possible.

We will be collecting some data from you that could be private (like your medical history, your name, and your birthdate for example). We will do everything we can to keep your privacy. Only the people that need the information for the study will see it. We will replace your name with a number on the study forms and questionnaires. There is a chance that someone else not working on the study might see your information, but we will try to make sure that doesn't happen.

OPTIONAL: Your parent or guardian will have the option of deciding if they would like to learn the results of the testing on your genes from the previous study in which you took part. If they decide they want these results, then we will ask for another blood or spit sample to check those results. This is optional. You do not have to give another sample if you or your parents do not want the earlier results, and you can still take part in the rest of this study. If you do give another blood sample, you could get a bruise or feel faint from the needle stick. You could get an infection from the needle, but that is not likely.

There may be other risks that we do not know about yet.

WHAT OTHER CHOICES ARE THERE?

Instead of being in this study, you can choose not to be in it. Take all the time you need to make your choice. Ask us any questions you have at any time. It is okay to say yes or no to the study. The study is voluntary – this means that you only say yes to the study if you want to do it. If you say yes, then later change your mind that is okay too.

SIGNATURES

After you have read this form and talked about this research with your parents and the doctors or nurses you need to decide if you want to be in this research.

If you want to be in this research you should sign or write your name below.

_____	_____
Child's Assent	Date
_____	_____
Signature of Person Obtaining Assent	Date