

**PEDIATRIC HEART NETWORK**  
**SVR (Single Ventricle Reconstruction)**  
**Extension Study**



*Information for Families of Patients with  
Hypoplastic Left Heart Syndrome  
and other Single Right Ventricle Defects*

At the time of your child's first surgery, he/she was enrolled in the Single Ventricle Reconstruction (SVR) trial, which looked at how infants with single ventricle heart defects did after surgery. Your child got one of two kinds of shunts: a modified Blalock-Taussig shunt or right ventricle to pulmonary artery shunt at the first stage of surgery (Norwood operation). Now, in the SVR follow-up study, we would like to learn if children do better with one of the two shunts in the years after surgery. Also we want to see how other medical and surgical factors affect children's health and how they develop. This study is being done at up to 15 other medical centers in the U.S. and Canada and is funded by the National Heart, Lung and Blood Institute of the National Institutes of Health.

#### **How do I join?**

In order for your child to participate in this study, you must sign an informed consent form.

#### **What tests are required during the study?**

If you join the SVR follow-up study, investigators will collect information regarding your child's development and heart function between ages 2 and 6 years. Information about how your child is doing will be collected from your child's medical records. There are no required study visits. In addition to our review of your child's medical records, we will collect certain items. These include:

**Questionnaires:** We will ask you to fill out surveys when your child is 3, 4, 5 and 6 years of age. The study nurse will explain the forms to you and how to fill them out. The questionnaires will ask you about your child's health and abilities, behavior, and quality of life, as well as about the impact of your child's heart problems and treatments on your family. These questionnaires may take about 1 to 2 hours each year to complete. Some surveys may be done while talking to the study nurse over the phone and some may be mailed to you to fill out and return.

**Holter Monitor:** When your child is 6 years old, we will measure his/her heart rate and rhythm with a Holter monitor. A Holter monitor makes a record over a 24-hour period. This small monitor will either be given to you or mailed to your home. Your child will wear patches on the skin and be connected to a

small box or recorder. The recording is painless, and your child will be able to have regular daily activity during this time. After a 24 hour recording, you will mail the monitor back to the study center. Your child's results will be shared with your child's cardiologist, who will tell you of any important findings.

**Echocardiograms:** An echocardiogram is a painless test using sound waves that takes a picture of your child's heart and is performed routinely in all children with heart disease. One or two of your child's echocardiograms that are done by your doctor as part of his or her routine clinical care will be reviewed for this study.

#### **Optional Study of Genes**

We will separately ask for your participation in future studies about which genes cause heart defects in children and how genes can affect a child's health. If you participate in this study, we will collect a detailed family history and blood or saliva samples from you/your child. If you do not want to join this separate study, your child may still remain in the SVR follow-up study.

#### **Follow-up after age 6 years.**

From the time that your child is 6 years old until he or she is 11 years old, we will phone you and review his/her medical record each year.

#### **Is there any cost?**

Tests required by the study that are not part of your child's regular care will be provided to you free of charge. These include the questionnaires and the Holter monitor. The study will also pay for all mailing expenses of questionnaires and the Holter monitor.

#### **Can I withdraw?**

Your decision to have your child participate in this study is completely voluntary. You may decline to participate or you may withdraw your child from the study at any time. Refusal to participate or withdrawal from the study will not affect your or your child's medical care now or in the future.

#### **Confidentiality**

You have a right to privacy and your child's participation in this research study will remain confidential. Your child's name will not be used in any published report of information from this study.

*Your and your child's participation in this research study will help to contribute to a better understanding of the best way to treat children with a single ventricle. Please consider taking part in this important research endeavor.*