Study Name: Long-term Outcomes of Children with HLHS and the Impact of Norwood Shunt Type (SVR III)- Informed Consent Templates

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INFORMED CONSENT TEMPLATE

Pediatric Heart Network

Study Title: Long-term Outcomes of Children with HLHS and the Impact of Norwood Shunt Procedure (SVRIII) Amendment

IRB Study Number:

Why is this research study being done?

As a baby, you were enrolled in the Single Ventricle Reconstruction (SVR) trial which aimed to see which shunt type was best for infants with single ventricle heart defects undergoing the Norwood operation. You received one of two kinds of shunts; a modified Blalock-Taussig shunt (MBTS) or right ventricle to pulmonary artery shunt (RV-to-PA shunt) as part of that study.
Then your parents had the option to enroll you in the Single Ventricle Reconstruction Extension study (SVR II)as we aimed to learn how children 2-6 years of age do with each of these shunt types and to improve our understanding of the medical and surgical factors which influence health and development for children with single ventricle heart disease.

After you were also invited to join Long-term Outcomes of Children with HLHS and the Impact of Norwood Shunt Procedure (SVRIII) which is a continuation of the two previous SVR studies. The purpose of SVR III study is to see which type of shunt placed at the time of the Norwood operation is most effective by later school age, beginning at 10 years of age. The goal was to learn if there are any long term differences in heart function, exercise ability, neurodevelopment, or quality of life between children who received a MBTS and those who received an RV-to-PA shunt. The study was designed to follow you until you were 16 years old.

Whether or not you participated in SVRII or SVRIII, we would like to continue to contact you and see how you are doing. This study is being performed with the support of the Pediatric Heart Network at all sites which participated in the original SVR trial. The work performed as a part of this study is supported by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH).

Why are you being asked to participate in this research study?

You are being asked to join this study because you participated in the original SVR, or SVR II or SVR III studies and we would like to continue to contact you and see how you are doing after turning 18 years old. As a part of the SVR study cohort, you were one of the largest groups of children with single ventricle heart disease, and have helped to answer important questions already.

The heart doctors and surgeons in the Pediatric Heart Network (PHN) Investigators want to understand how the children who participated in the SVR Trial are doing many years after surgery. You are part of a special group of children and your health and well-being are important as we learn how to care better for other children with similar heart problems.

How long will you be in the study and what will happen during the study?

If you agree to continue to be part of this study, you will be contacted once so we can talk about your medical care since your last study visit and collect current contact information.

What are the risks and discomforts of the research study?

Your personal identifying information will not be kept in any other records outside of this institution, information about your medical care since your last visit will be shared with the PHN Data Coordinating Center but you will not be identified by name.

Are there benefits to taking part in the research study?

You may receive no direct benefit from the study. However, the possible benefit of participation is as follows:

> There might be an indirect benefit from the awareness that through your participation, these study results may help to improve the care of children with similar problems in the future.

Do you need to give your consent in order to participate?

If you decide to participate in this study amendment, you must sign this form. A copy of the consent forms will be given to you to keep as a record.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to join in order to receive care at***<institution>.*** If you do not want to participate in this study, you will continue to receive standard medical care by your doctors. You will continue to take any medications prescribed by your doctor. Your doctor will talk with you about your choices for treatment along with the risks and benefits.

Can you stop your participation in the study early?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes except for data that relates to an adverse event (a bad effect) of the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes and any new information about an adverse event related to the study will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled and will not affect your \access to health care at X institution or anywhere else. If you do decide to withdraw \, we ask that you contact Dr. ***[PI]*** in writing and let [him/her] know that you are withdrawing \ from the study. [His/her] mailing address is ***[address].***

Your participation in this study will be stopped if at any time it is determined by your doctor to be in your best interest.

Can the study doctor take you out of the study early?

The study doctor may also take you out of the study because:

- We stop doing the study for other reasons

If this happens, the study doctor will explain why you need to stop taking part in the study.

What are your rights as a participant?
Your participation in this study is completely voluntary. You should not feel any pressure to join. If you do not want to participate in the study, it will not affect the care you receive here at ***<institution>*.**

You have the right to ask questions about this study at any time. The study doctor or a member of his/her staff will answer questions you may have about this study. If you have any questions about your rights as a research participant, you may contact *<insert contact name/number>.*

If you agree to participate in the study, we will inform you of any new information that might affect your willingness to participate in the study. *We will also provide you a summary of the study findings, after the study is completed and the results are published.*

If you agree to participate in the study, you may withdraw from the study at any time. If you do decide to withdraw, it is important that you contact *<site PI>* and let him/her know.

If you decide to withdraw from the study, no new information about you will be collected for study purposes unless the information concerns an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review you entire medical record. The reason for withdrawal will be documented for all participants withdrawn from the study.

How will your information be kept confidential and private?
We will do everything we can to keep your medical and research data private.
<site/institution>and/or ***<site PI>*** will do the following things to maintain your privacy:

- Your will be given a study identification (ID) number. All study records and questionnaires will be labeled with this number and not your name or other personal data. The files that link the ID number to you will be kept in a locked, secure area that only the study team can open.
- As part of your participation in this study, a unique participant number called a Global Unique Identifier (or GUID) will be assigned to you that will allow researchers to see if you have been in more than one research study or database. If you have participated in more than one such study or database, this GUID may prevent information from being used more than once by mistake. This GUID will also allow you de- identified information to be combined with information from other research to increase the likelihood of meaningful results. Only this GUID, and not identifiable information, will be available to other researchers.

- We will ask you to sign a release of information so that we can contact your doctor(s) or hospital(s) to obtain copies of your medical records for the length of the study. The information will be kept confidential and no identifying information will be shared outside the study team and your healthcare providers.

- Data gathered during this study and medical records may be checked and verified by staff of the NIH, <***site/institution***>Institutional Review Board, or the Pediatric Heart Network Data

Coordinating Center. All medical records from this site or from other institutions that have personal identifiers will be treated as private and will be shared only with these agencies, or as required by law. In the case of safety, patient data will only be given to the Data Coordinating Center *the* <***site/institution***>Institutional Review Board and NIH/NHLBI, if needed.

- The results of this study may be published for all the participants as a group but will not identify you individually.

At the end of the study, participants will be sent a description of the overall study results in lay language. Contact information for the study PI and/or coordinator will be provided, in the event the family wishes to discuss the results or has questions. A separate notification will also be provided to the treating/referring physician (cardiologist, etc.) describing overall study results.

Clinical Trials Website: A description of this study will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

<INSERT SITE-SPECIFIC HIPAA TEXT HERE>

Will it cost you anything to be in this study?

There will be no extra costs to you when you join this study. You must pay for all other costs related to your normal medical care such as hospital stays, surgery, drugs, lab tests, and doctor's fees which are thought to be standard medical care for patients with your condition.

Will you be paid to join this study?

No payment will be given for participating in this study amendment.

What happens if you believe you are injured during this study?

Immediate necessary medical care is available at <***site/institution***> *in the event that you are injured as a result of being in this research study. However, there is no promise by* <***site/institution***>*, Dr.* <***site PI***> *or your* <***site***> *physicians to repay costs or give free medical care to you in the event of a study-related injury. Further information concerning this and your rights as a research participant can be obtained from the* <***site/institution***> *Institutional Review Board (IRB) Office at:* <***phone number***>*.* (Or insert institutional language).

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

If you have questions about this study, you should contact:

<Site PI>, MD Telephone Number: <telephone number>

Pager Number: <pager number>

If you have questions or want more information about the Pediatric Heart Network or about being in

a study, you may go to www.PediatricHeartNetwork.org and www.ChildrenAndClinicalStudies.nhlbi.nih.gov

If you have questions concerning your rights as a participant in this study, you should contact: <Site> Institutional Review Board (IRB) Office at:

Telephone Number: <phone number>

CONSENT:
The purpose of this study, what will happen, risks and benefits have been explained to me. I have been allowed to ask questions and my questions have been answered to my satisfaction. I have been told who to contact if I have more questions. I have read this consent form and agree to be in this study. I understand that I am free to withdraw this consent and stop from being in this study at any time, even after signing this form, and it will not affect my care. By signing this form, I agree to follow the instructions given by the research staff during the study. I have been told that I will be given a signed copy of this consent form.

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent Date:
Name of Participant	
Signature	Date
Name of Authorized Representative (if different than participant)	Relation to participant:
Signature of Authorized Representative	Date