

**Congenital Heart Surgeons' Society (CHSS)  
Studies of Congenital Heart Disease  
RESEARCH CONSENT FORM PARENT VERSION**



**Name:**

**Date of Birth:**

**HSC #:**

**Consent Form Version Date: November 26, 2008**

**Title of Research Project: Congenital Heart Surgeons' Society (CHSS) Studies in Congenital Heart Disease**

**Investigator(s):**

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**Purpose of the Research:**

You and your child are being asked to participate in a research study to help us understand more about your child's heart condition. The Congenital Heart Surgeons Society (CHSS) Data Center is a registry designed to collect information about children with congenital heart disease from many centers in the United States and Canada. Because children with congenital heart disease have many different and sometimes rare conditions, compiling information from multiple centers is necessary to determine which factors are associated with better or worse outcomes. The analysis of this patient information has helped surgeons to choose the best treatment for children with different types of defects, and has helped them to inform parents and patients what the outlook for the future might be.

**Description of the Research:**

If you/your child participate in this study, information regarding your child's surgery and hospitalization will be sent to the CHSS registry's center at the Hospital for Sick Children in Toronto, Canada. All of this information will be kept confidential. Information such as your child's diagnosis, anatomy, surgical procedures, and follow-up status will be entered into a computer database. No special investigations or interventions will be performed for this study. We will simply collect information about your child's hospitalization and surgery and subsequent routine follow-up visits.

Specially trained personnel from the CHSS Data Center or from your child's hospital will contact you on a yearly basis, checking on your child's progress for the year. Information about your child together with the data from other children with the same diagnosis from 40 CHSS centers will be entered into a database and analysed. The results will form the basis for scientific

reports, and will be shared regularly at meetings of the CHSS, attended by the world's leading pediatric heart surgeons. If changes are made to the study or new information that might affect your willingness to continue to participate in the research becomes available, you will be informed.

**Potential Harms Injuries, Discomforts or Inconvenience:**

There are no foreseeable risks and/or discomforts associated with participating in this study. If you agree to participate in this study, your child's diagnostic testing and surgery will not be altered in any way. All records associated with your child's participation in this study will be strictly confidential and maintained securely within the registry. Your child's name or any other identifying information name will not be released to any outside individuals or used in any publications.

**Potential Benefits:**

Information collected by this registry may contribute to the care of future children with the same heart condition as your child. The information may improve the future management of your child.

**Confidentiality:**

Confidentiality will be respected and no information that discloses the identity of the subject will be released or published without consent unless required by law. This legal obligation includes a number of circumstances, such as suspected child abuse and infectious disease, expression of suicidal ideas where research documents are ordered to be produced by a court of law and where researchers are obliged to report to the appropriate authorities. For your information, the research consent form will be inserted in the patient health record. Health records identifying the patient may be given to and inspected by the SickKids Clinical Research Office Monitor. If you/your child withdraw from the research study, information that has already been collected will be part of the research data, but no further information will be sought or used.

**Participation:**

Participation in this research project is voluntary. If you choose not to participate, you and your family will continue to have the same access to health care. If you choose on behalf of your child to participate in this study you can withdraw from the study at any time. New findings developed during the course of the research which may impact on your willingness to continue will be provided to you and your consent will be requested again, if necessary. You will be given a copy of this consent form for your records. If you become ill or are injured as a result of participation in this study, medical treatment will be available at no additional cost to you. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities.

**Sponsorship:**

The sponsor of this research is the Congenital Heart Surgeons' Society - In certain situations, this study may be cancelled at the discretion of the investigator or the study sponsor even if you are benefiting personally. If this occurs, the investigator will discuss next steps with you.

**Consent:**

Consent Form Version: November 2008

By signing this form, I agree that:

- 1) The study has been explained to me. All my questions were answered.
- 2) The possible harms and discomforts and the possible benefits (if any) of this study have been explained to me.
- 3) I know about the alternatives to having my child take part in this study. I understand that I have the right to refuse their participation and the right to stop at any time. My decision about whether or not to participate will not affect my child's health care at The Hospital for Sick Children.
- 4) I am free now, and in the future, to ask any questions about the study.
- 5) I have been told that my child's medical records will be kept confidential, except where release of information is required by law, e.g., suspected child abuse, public health.
- 6) I understand that no information that would identify my child will be released or printed without asking me first.

I hereby consent for my child to participate. I have read and understood all pages of this consent form.

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*Name of Parent*

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*Signature & Date*

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*Name of person who obtained consent*

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*Signature & Date*

For answers to questions about research subjects' rights and research-related injury, please contact the Research Ethics Board Manager at (416) 813-5718.