RESEARCH CONSENT FORM [PARENT/GUARDIAN]

Title of Research Study:
Atrioventricular Septal Defect – A Congenital Heart Surgeons' Society Inception Cohort Study

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You are being asked to consider letting your child participate in a research study. A research study is a way of gathering information or to answer a question about something that is not well understood. This research study is about the condition your child has called Atrioventricular Septal Defect (AVSD). This consent form explains the purpose of this research study, and gives you all the information about the study, the procedures involved, possible risks and benefits and your rights. Please read this form carefully and ask any questions you may have. If you wish, someone may be available to verbally translate this form into your preferred language. You may take as much time as you wish to decide whether or not to participate. Feel free to discuss it with your friends and family, or your family doctor. Please ask the study staff or one of the Investigators to explain anything you do not understand or would like to know more about. Make sure all your questions are answered before deciding whether to participate in this research study. Participating in this study is your choice (voluntary). You have the right to choose not to participate, or to stop participating in this study at any time.

Purpose of the Research:
The broad purpose of the research study is to gather information about children with Atrioventricular Septal Defect (AVSD) from across North America to help understand and improve the lives of future patients. We want to see if there are any differences in outcome after diagnosis in those children who have different types of heart operations. Using the information in this study, we hope to find which treatment options are best. We can only accomplish these goals through the collaboration of multiple hospitals and institutions. You are being invited to take part in this registry on behalf of your child because your child has AVSD. A registry is a place where data, records, and sometimes laboratory samples are kept and made available for research. This study has been ongoing since 2012 and since that time an average of about 75 subjects are being enrolled into the study each year.

Description of the Research:
This proposed study will be carried out through participating hospitals of the Congenital Heart Surgeons' Society, with the data stored and typically analyzed at the CHSS Data Center. The CHSS is a professional organization of approximately 170 surgeons from approximately 70 hospitals in the United States, Canada, and South America. They all share a common interest in treatment and management of

congenital heart disease (birth defects in the heart) and are committed to research in this area. This group collects information on children with congenital heart disease from many different centers in Canada and the United States and in South America. This information is kept in a secure and confidential registry at the CHSS Data Center, at The Hospital for Sick Children (SickKids) in Toronto, Ontario, Canada. The investigators of this study and SickKids participate in this study as a member of the Congenital Heart Surgeons' Society. Since children with congenital heart disease have many different and sometimes rare conditions, gathering information from many hospitals gives us better information on how children with congenital heart disease are doing. We also learn what factors and treatments have a better or worse result.

Study Procedures

If you decide to let your child take part in this study and sign the informed consent form, you will allow research staff within the hospital to review your child's medical chart for information on your child's medical history, including tests performed at the time of his/her diagnosis and afterwards, and medications he/she has taken or may be currently taking.

This is an observational study. It does not involve administering medications or treatment/procedures other than those that your child would normally need. Information about your child's hospitalizations will be sent to the CHSS Data Center. Information such as your name and address, and your child's name and address, date of birth, and phone numbers, your child's diagnosis, pediatrician's name and address, medical and surgical reports, copies of echocardiograms, chest x-rays, exercise tests, nuclear medicine scans, MRI, CT scans, and cardiac catheterizations and follow up health status will be entered into a secure password-protected computer database. Once this information is collected and sent to the CHSS Data Center, a unique study identification number will be created for your child so that personal health information is not used directly in any further analysis. Videotapes or compact discs of your child's echocardiograms, nuclear perfusion scans, MRI, and/or CT scans will also be securely forwarded to the Data Center, and de-identified. Your child will not be required to undergo any special tests or procedures to participate in this study. We will simply collect information about your child's hospitalization and surgery and subsequent routine follow-up visits.

Upon enrollment and registration into the study, a staff member of the CHSS Data Center will contact you to welcome you into the study and review the study follow-up plan with you. Every year, a member from the CHSS Data Center will contact you to update your contact information and see how your child is doing. The study questionnaires that you and your child (if applicable) will be asked to complete and send back to the CHSS Data Center, or complete over the phone, are related to your child's health. The questions are about the medications your child is receiving, which conditions or problems your child has, any exercise limitations, and any surgery or procedures done, and your child's overall quality of life. These should not take longer than 15-20 minutes to complete. Your child's information, along with the information of other participants with the same heart defect from other centers, will be analyzed together, to determine the impact that various patient factors and different treatments have on the overall health status and quality of life of children with AVSD. The aggregated (combined) results will form the basis for scientific reports, and will be shared regularly at meetings of the CHSS, attended by the world's leading congenital heart surgeons.

If in the future your child's clinical follow up is at another hospital/institution that is not participating in this study, and we need to obtain some of your child's cardiac-related medical or surgical follow-up reports/records from that institution, we will contact you to discuss options for this. We may request at that time that you sign a Consent for Release of Medical Information so we can obtain the required

information. This would not result in any costs or expenses to you, and it would be entirely up to you whether you decide at that time to provide your consent for that or not.

We would like to continue to follow the patients who participate in this study throughout their lifetime to evaluate long-term outcomes of AVSD. By agreeing to participate in this study you are giving permission for the investigators/study team members and the CHSS Data Center to contact you annually, as mentioned above.

Visit Schedule
There will not be any regularly scheduled visits for the study. Please continue with your child's regularly scheduled doctor's visits. You and your child (as applicable) will have questionnaires to answer annually until your child is 18 years old or able to provide consent for him/herself for study participation. After that, he/she will be asked to provide consent to continue participation in the study.

Potential Harms:
We know of no harm that taking part in this study could cause your child. The only potential risks are related to collection and sharing of your child's health information. Every effort will be made to protect your child's privacy when participating in the study. There are no consequences if you do not agree on behalf of your child to participate in the study.

Potential Discomforts or Inconvenience:
This study only involves the collection and analysis of available clinical information, along with yearly questionnaires, so there are no additional discomforts from participating in this study. The only potential inconvenience associated with participation in this study is the time commitment required to participate, which is only about 15-20 minutes per year.

Potential Benefits:
To Individual Subjects:
The information collected by this study may contribute to the care of children in the future who have the same heart condition as your child. The information may also improve the future management of your child's heart condition. However, your child will not benefit directly from participating in this study. Results of the study will not be shared directly with you or your child. However these will be available in the scientific publications resulting from this work.
To Society:
Society in general or patients with a similar heart condition may benefit from the results of this study, as explained above.

Alternatives to Participation:
We would like to assure you that your child's participation in this research is optional, and should you or your child decide not to participate, your child's normal clinical care would go on undisturbed.

Confidentiality:
We will respect your/your child's privacy. No information about who your child is will be given to anyone or be published without your permission, unless required by law. For example, the law could make us give information about you if your child has been abused, if you or your child have an illness that could spread to others, if you or someone else talks about suicide (killing themselves), or if the court orders us to give them the study papers.

If you decide to participate in this study, the Investigators and study staff and the CHSS Data Center staff will look at your child's personal health information and collect only the information they need for this study. Personal health information is health information about your child that could identify him/her because it includes information such as name, address, telephone number, date of birth, new and existing medical records, or the types, dates and results of various tests and procedures. You have the right to access, review and request changes to your child's personal health information.

SickKids Clinical Research Monitors, the Congenital Heart Surgeons' Society, and Saving tiny Hearts Society, or the regulator of the study may see your child's health record to check on the study. By signing this consent form, you agree to let these people look at your child's records. We will put a copy of this research consent form in your child's patient health record at SickKids and give you a copy as well.

The Investigators, study staff, the CHSS Data Center and the other people listed above will keep the information they see or receive about your child confidential, to the extent permitted by applicable laws. Even though the risk of identifying your child from the study data is very small, it can never be completely eliminated. The Investigators and study staff and the CHSS Data Center will keep any personal health information about your child stored in a secure location for 7 years after all study publications are completed and then it will be securely destroyed according to the institutional policy effective at that time. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Published study results will not reveal your or your child's identity. You have the right to be informed of the results of this study once the entire study is complete.

Study data are health information about your child that are collected for the study, but that do not directly identify him/her. The data produced from this study will also be stored in a secure, locked location. Only members of the research team (and possibly those individuals described above) will have access to the data. This could include external research team members. Any study data about your child that are sent outside of the hospital will have a code and will not contain your child's name or address, or any information that directly identifies him/her. Study data that are sent outside of the hospital will be used for the research purposes explained in this consent form.

Reimbursement:

Will there be any costs to you or your child?

There is no cost to you or your child for participating in this study.

Will you or your child be paid for taking part in this study?

Neither you nor your child will be reimbursed for taking part in this study.

Participation:

Participation in research is voluntary. If you choose to let your child take part in this study you can take your child out of the study at any time. The care your child gets at SickKids will not be affected in any way by whether your child takes part in this study.

New information that we get while we are doing this study may affect your or your child's decision to continue to take part in this study. If this happens, we will tell you about this new information. We will ask you and your child (as applicable) again if you still want to be in the study.

During this study we may create new tests, new medicines, or other things that may be worth some money. Although we may make money from these findings, we cannot give you or your child any of this money now or in the future just because your child took part in this study.

You have the right to receive all information that could help you make a decision about letting your child participate in this study. You also have the right to ask questions about this study and your child's rights as a research participant, and to have them answered to your satisfaction, before you make any decision. You also have the right to ask questions and to receive answers throughout the study.

If your child becomes ill or is harmed because of study participation, we will treat your child for free. Your signing this consent form does not interfere with your legal rights in any way. The staff of the study, any people who gave money for the study, or the hospital are still responsible, legally and professionally, for what they do.

The Hospital for Sick Children has reviewed this study. If you have any questions about your child's rights as a research participant or any ethical issues related to this study that you wish to discuss with someone not directly involved with the study, you may call the Office of the Research Ethics Board at 416-813-8279 during business hours.

Sponsorship:
The Congenital Heart Surgeons' Society is sponsoring this study.

Conflict of Interest:
The Investigators and the other research team members have no conflict of interest to declare.

Consent to Participate in a Research Study

Study Title: Atrioventricular Septal Defect – A Congenital Heart Surgeons' Society Inception Cohort Study

By signing this research consent form, I understand and confirm that:

1. All of my questions have been answered,
2. I understand the information within this informed consent form,
3. I allow access to my child's medical records as explained in this consent form,
4. I do not give up any of my or my child's legal rights by signing this consent form,
5. I understand that my child's health care provider may be informed of my participation in this study
6. I have been told I will be given a signed and dated copy of this consent form.
7. I agree to allow the person for whom I am responsible to take part in this study.

I consent on behalf of _____ (name of child) to participate in this study.

Printed Name of Parent/Guardian	Parent/guardian signature	Date (DD/MMM/YYYY)

Printed Name of person who obtained consent	Role of person obtaining consent	Signature	Date (DD/MMM/YYYY)

If the participant/surrogate decision maker was assisted during the consent process:
Please check the relevant box and complete the signature space below:

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and appeared to be understood by the participant.
☐ The person signing below acted as a translator for the participant during the consent process.
Language: _____

Name (print)	Signature	Date (DD/MMM/YY)