RESEARCH CONSENT FORM [SUBJECT]

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 participating 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 you have 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.

When you were a baby/child, your parent/guardian signed the consent form for participation in this study. Now you are making your own decisions about continuing in this research study.

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 because you have 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 take part in this study and sign the informed consent form, you will allow research staff within the hospital to review your medical chart for information on your medical history, including tests performed at the time of your diagnosis and afterwards, and medications you have taken or may be currently taking.

This is an observational study. It does not involve administering medications or treatment/procedures other than those that you would normally need. Information about your surgical procedures and hospitalizations will be sent to the CHSS Data Center. Information such as your name and address, date of birth, and phone numbers, your diagnosis, physician'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 assigned so your personal health information is not used directly in any further analysis. Videotapes or compact discs of your echocardiograms, nuclear perfusion scans, MRI, and/or CT scans will also be securely forwarded to the Data Center, and de-identified. You will not be required to undergo any special tests or procedures to participate in this study. We will simply collect information about your hospitalizations and surgical procedures 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 you are doing. The study questionnaires that you and your parent (if applicable) will be asked to complete and send back to the CHSS Data Center, or complete over the phone, are related to your health. The questions are about the medications you are receiving, any exercise limitations, and any surgery or procedures done, and your overall quality of life. These should not take longer than 15-20 minutes to complete. Your 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 individuals 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 your clinical follow up is at another hospital/institution that is not participating in this study, and we need to obtain some of your 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 regularly scheduled doctor's visits. You will have questionnaires to answer annually throughout your life while you are participating in this study. Your parent may be asked to complete similar study questionnaires as well.

Potential Harms:

We know of no harm that taking part in this study could cause you. The only potential risks are related to collection and sharing of your health information. Every effort will be made to protect your privacy when participating in the study. There are no consequences if you do not agree 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 yours. The information may also improve the future management of your heart condition. However, you will not benefit directly from participating in this study. Results of the study will not be shared directly with you. 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 participation in this research is optional, and should you decide not to participate your normal clinical care would go on undisturbed.

Confidentiality:

We will respect your privacy. No information about who you are 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 you 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 personal health information and collect only the information they need for this study. Personal health information is health information about you that could identify you because it includes information such as your 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 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 health record to check on the study. By signing this consent form, you agree to let these people look at your records. We will put a copy of this research consent form in your patient health record at SickKids (if applicable) 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 you confidential, to the extent permitted by applicable laws. Even though the risk of identifying you 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 you 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 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 you that are collected for the study, but that do not directly identify you. 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 you that are sent outside of the hospital will have a code and will not contain your name or address, or any information that directly identifies you. 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?

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

Will you be paid for taking part in this study?

You will not be reimbursed for taking part in this study.

Participation:

Participation in research is voluntary. If you choose to take part in this study you can decide to stop your participation in the study at any time. The care you get will not be affected in any way by whether you take part in this study.

New information that we get while we are doing this study may affect your decision to continue to take part in this study. If this happens, we will tell you about this new information. We will ask you 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 any of this money now or in the future just because you took part in this study.

You have the right to receive all information that could help you make a decision about participating in this study. You also have the right to ask questions about this study and your 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 you become ill or are harmed because of study participation, we will treat you 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 questions about your 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 member 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 medical records as explained in this consent form,
4. I do not give up any of my legal rights by signing this consent form,
5. I understand that my 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 take part in this study.

I consent to participate in this study.

Printed Name of Participant	Participant 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)