SickKids
THE HOSPITAL FOR SICK CHILDREN
Research Ethics Board

RESEARCH CONSENT FORM AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION [PARENT/GUARDIAN]

Title of Research Study:
Determining the Natural and "Unnatural" History of Anomalous Aortic Origin of a Coronary Artery with Interarterial or Intraconal or Intramural course (AAOCA): Establishing a Multi-Institutional Registry

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Please address all questions to:		
CHSS Data Center	Toll Free Line	1-866-477-2477

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 AAOCA. 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 registry is to gather information across North America from all children and young adults to help understand and improve the lives of patients with AAOCA. We want to see if there are any differences in outcome after diagnosis in those children who have surgery compared with those who do not. Using the information in this registry, we hope to find which treatment options are best in order to reduce the risk of decreased blood flow to the heart while allowing people with AAOCA to ultimately lead a normal quality of life. Because AAOCA is rare, we can only accomplish these goals through the collaboration of multiple hospitals and institutions. Your child is being invited to take part in this registry because he/she has anomalous aortic origin of a coronary artery (AAOCA). A registry is a place where data, records, and sometimes laboratory samples are kept and made available for research. Up to approximately 70 medical centers will take part in the study. This study has been ongoing since 2009 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 member institutions of the Congenital Heart Surgeons' Society (CHSS), with the data stored and typically analyzed at the CHSS Data Center. The CHSS is a group 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 malformations 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. Since children with congenital heart disease have many different and sometimes rare conditions, gathering information from many centers 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 information will be entered into a database.

There will be no additional exams for this study. All exercise tests, echocardiograms, and other forms of monitoring are performed as standard of care.

Information about your child's diagnosis, tests, and hospitalization/surgery (if applicable) will be kept in the CHSS Data Center. Information such as your name and address, your child's name and address, date of birth, and phone numbers; your child's diagnosis; your child's 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, 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 scan, 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 find out 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 AAOCA. 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 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 AAOCA. 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. In addition, this study will address the steps required to create a risk stratification model using the infrastructure of the CHSS to rapidly develop the only registry of children and young adults with AAOCA ever assembled.

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 that discloses the identity of your child will be released or published without your consent 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, employees of the funder or sponsor, the Congenital Heart Surgeons' 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 child's identity. You have the right to be informed of the results of this study once the entire study is complete.

Study data is health information about your child that is collected for the study, but that does 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 maybe those individuals described above) will have access to the data. This could include external research team members. Any study data about your child that is 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 is 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 receive any payments 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 and your child still want to be in the 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.

During this study we may create new tests 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.

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 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 Research Ethics Manager at 416-813-5718.

Sponsorship:

The Congenital Heart Surgeons' Society, The Children's Heart Foundation, The Michael H. Ludwig Memorial Foundation, The Cardiac Center at The Children's Hospital of Philadelphia and The Hospital for Sick Children are sponsoring this study.

Conflict of Interest:

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

Consent:

By signing this form, I agree that:

1) You have explained this study to me. You have answered all my questions.
2) You have explained the possible harms and benefits (if any) of this study.
3) I know what I could do instead of having my child take part in this study. I understand that I have the right to refuse to let my child take part in the study. I also have the right to take my child out of the study at any time. My decision about my child taking part in the study will not affect my child's health care at SickKids.
4) I am free now, and in the future, to ask questions about the study.
5) I have been told that my child's medical records will be kept private except as described to me.
6) I understand that no information about my child will be given to anyone or be published without first asking my permission.
7) I have read and understood pages 1 to 6 of this consent form. I agree, or consent, that my child _____ may take part in this study.
   Printed Name of Child

_____	_____
Printed Name of Parent/Legal Guardian	Signature & Date
_____	_____
Printed Name of Person who explained consent	Signature & Date
_____	_____
Printed Name of Witness (if the Parent/Legal Guardian does not read English)	Signature & Date

If you have any questions about this study, please call the Congenital Heart Surgeons' Society (CHSS) Data Center, Toll Free, at 1-866-477-2477.

If you have questions about your rights as a subject in a study or for information on whom to contact in the event of injuries during a study, please call the Research Ethics Manager at 416-813-5718.