SickKids
THE HOSPITAL FOR SICK CHILDREN
Research Ethics Board

RESEARCH CONSENT FORM AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION [SUBJECT]

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

Investigators:		**Telephone No.:**
Dr. Christopher A. Caldarone	Division of Cardiovascular Surgery	416-813-7794
Dr. Brian W. McCrindle	Division of Cardiology	416-813-7610
Dr. William G. Williams	Division of Cardiovascular Surgery	416-813-6419

Research Team Members:		
Susan McIntyre, RN	CHSS Data Center	416-813-7654 ext. 203708
Kristina Kovach, RN	CHSS Data Center	416-813-7654 ext. 201791

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

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 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.

If you were enrolled in this study when you were a child, your parent/guardian would have 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 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. You are

being invited to take part in this registry because you have 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 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 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 diagnosis, tests, and hospitalization/surgery (if applicable) will be kept in the CHSS Data Center. Information such as your name and address, date of birth, and phone numbers; your diagnosis; your doctor'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 you so that personal health information is not used directly in any further analysis. Videotapes or compact discs of your echocardiograms, nuclear perfusion scan, 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 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 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 of individuals 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 your clinical follow up is at another hospital/institution that is not participating in this study, and we need to obtain some of your 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 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 individuals 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. 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 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 that discloses your identity will be released or published without your consent unless required by law. For example, the law could make us give information about you if a child has been abused, 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, employees of the funder or sponsor, the Congenital Heart Surgeons' 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 is health information about you that is collected for the study, but that does 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 maybe those individuals described above) will have access to the data. This could include external research team members. Any study data about you that is 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 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?
There is no cost to you for participating in this study.
Will you be paid for taking part in this study?
You will not receive any payments for taking part in this study.

Participation:
Participation in research is voluntary. If you choose to take part in this study you can get out of the study at any time. Your care 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.

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.

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 any of this money now or in the future just because you took part in this 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 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 participating in this study. I understand that I have the right not to take part in the study and the right to stop at any time. My decision about taking part in the study will not affect my health care in any way.
4) I am free now, and in the future, to ask questions about the study.
5) I have been told that my medical records will be kept private except as described to me.
6) I understand that no information about me 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, to participate in this study.

_____	_____
Printed Name of Subject & Age	Signature of Subject & Date
_____	_____
Printed Name of Person who explained consent	Signature of Person who explained consent& Date
_____	_____
Printed Name of Witness (if the Subject does not read English)	Signature of Witness & 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.