VERBAL CONSENT TO PARTICIPATE IN A RESEARCH STUDY AND AUTHORIZATION TO USE AND DISCLOSE IDENTIFIABLE PRIVATE HEALTH INFORMATION

Study Title: 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

Principal Investigator: Dr. Christopher A. Caldarone

Version: Parent/Guardian of Child Participant/Subject or Adult Participant/Subject

Hello, my name is _____. I am a study coordinator from the Division of Cardiovascular Surgery at The Hospital for Sick Children. Is this a good time to talk to you? *If "YES" proceed," if "NO", make arrangements for a convenient time*.

We are conducting a study on anomalous aortic origin of a coronary artery (or AAOCA). [*You; You (on behalf of your child)*] are being invited to participate in this research study because [*you have; your child has*] AAOCA. Your participation in this study is completely voluntary. This means that [*you; you (on behalf of your child)*] do not have to participate in this study unless you want to. If there is anything you do not understand, please ask questions.

Would you be interested to hear more about this study?
If "YES", proceed; if "NO" thank the individual for his/her time and end the call.

The use of "you" in this consent form is in reference to Adult Participant/Subject, and the use of "your child" is in reference to Parent/Guardian of Child Participant/Subject, as applicable.

Good. The purpose of this research study is to develop a registry of children and young adults with AAOCA. A registry is a place where data, records and sometimes laboratory samples are kept and made available for research. This registry will collect and analyze clinical information from children and young adults who have AAOCA across North America and South America too. Using the information we obtain from/about [*you; your child*] and others with AAOCA, we hope to find which treatment options are the best to enable people with this condition to ultimately enjoy a normal quality of life.

We estimate that approximately 1,000 to 1,500 subjects will enroll in this study overall. 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.

This proposed study will be carried out through participating member institutions of the Congenital Heart Surgeons' Society (CHSS), with the data securely stored at the CHSS Data Center, and typically analyzed there as well. The CHSS is a group of approximately 170 surgeons from approximately 70 hospitals/institutions in the United States, Canada and South

America. This group collects information on children with congenital heart disease from many different centers in Canada and the United States, and in South America too. This information is kept in a secure and confidential registry at the CHSS Data Center at The Hospital for Sick Children in Toronto, Ontario, Canada.

If you agree to participate in this research, we would like your permission to view [*your; your child's*] medical records to obtain additional information about [*your; your child's*] medical care. We would also like permission for specially trained personnel from the CHSS Data Center to contact you on a yearly basis throughout [*your; your child's*] life [*for child: until he/she is an adult (18 years old)*] to ask you several questions regarding [*your; your child's*] health status, medical care and demographics. These questions will only take about 15-20 minutes to answer at your convenience. Once we have your verbal consent to participate, we will mail you a written consent form which will highlight and go into further details regarding what we have spoken about today. By signing the consent form and returning it to us in the self-addressed stamped return envelope, you are agreeing to what we have discussed today and are allowing us to send [*your; your child's*] medical record data confidentially and securely to the CHSS Data Center.

If you agree [*to participate; to have your child participate*] in the registry, the only additional requirements will be to answer several health-related questions once a year throughout [*your life; your child's life until he/she is an adult (18 years old), after which he/she will be asked to participate in the study him/herself*]. There will be no additional exams for this study. All exercise tests, echocardiograms and other forms of monitoring will continue to be performed as standard of care according to [*your; your child's*] heart doctor.

Participation in this study is voluntary; you do not have to take part in order [*to receive; to have your child receive*] care at The Hospital for Sick Children. If you decide not to take part or if you change your mind there will be no penalties or loss of any benefits to which [*you are; your child is*] otherwise entitled. [*Your; Your child's*] current and future medical care at The Hospital for Sick Children will not be affected by your decision.

What are the risks of this study?

As this study involves only collection and analysis of available clinical information, along with yearly questionnaires, there are no additional discomforts from participating in this study. There are no risks associated with answering the questions on the annual questionnaires. The only potential risks are related to collection and sharing of [*your; your child's*] health information. Every effort will be made to protect [*your; your child's*] privacy when participating in the registry.

Any significant new findings that may affect health, welfare or willingness to stay in the study will be given to you.

Are there any benefits to taking part in this study?

There will be no direct benefit to [*you; your child*] from taking part in this study. The information collected by this study may contribute to the care of children and adults in the future who have [*your; your child's*] same heart condition. Personal benefit is not guaranteed, but knowledge may be gained that will benefit all current and future individuals with AAOCA.

Are there alternatives to participation in this study?
The other option for [*you; you on behalf of your child*] other than this study is to not participate in this study.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?
We need to collect health information about [*you; your child*] in order to conduct this study. This includes information about [*you; your child*] from medical records and from the questionnaires that are part of this research. Only regulators, members of the research team, medical staff involved in [*your; your child's*] care and people who oversee or evaluate research and care activities at The Hospital for Sick Children will be allowed to access [*your; your child's*] information. Other groups including our study sponsors, 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, and Healthcare professionals and specially trained research staff members at the CHSS Data Center who are helping in our data collection and analysis may also have access to study data that identifies [*you; you and your child*]. We will keep [*your; your and your child's*] identity private in any publication or presentation about the study. However, we cannot guarantee absolute confidentiality; some of the organizations may not be required to protect [*your; your child's*] information under the same federal and provincial privacy laws. If permitted by law, they may be allowed to share it with others without your permission. By participating in this study, you are authorizing The Hospital for Sick Children to use and/or release [*your; your child's*] health information for this research.

The information collected as part of this study will be securely retained for 7 years after all study publications are completed. At that time, the research information 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. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

You may change your mind and take back your authorization to use and disclosure [*your; your child's*] health information at any time. Even if you take back your authorization, we may still use and disclose the health information we have already obtained about [*you; your child*] as necessary to maintain the integrity or reliability of the current research. To take back your authorization, you must let the study doctor, Dr. Christopher A. Caldarone, or the study staff know that you changed your mind and do not want us to collect any more health information about [*you; your child*].

Financial Considerations
There is no charge or payment to [*you; you or your child*] related to participation in this study.

What if you have questions about the study?
If you have questions about the study, call the study doctor, Dr. Christopher A. Caldarone, at 416-813-7794, or the CHSS Data Center, toll free line, at 1-866-477-2477 to speak to one of the research team members. You may also talk to your own doctor if you have questions or concerns.

The Research Ethics Board (REB) at The Hospital for Sick Children has reviewed and approved this study. The REB looks at research studies like this one and makes sure [*your; your and your child's*] rights and welfare are protected. You can talk to a person from this group if you have questions about [*your; your and your child's*] rights as someone taking part in a research study. You can call the REB Office at 416-813-5718 if you have questions or complaints about the study.

Do I have your permission to enroll [*you; your child*] in this study? *(If "YES", proceed)*

Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date

Name of [*Subject; Parent/Guardian*]

Child's Assent [as applicable]

For children <u>capable</u> of providing assent:

I have explained this study and the procedures involved to _____ [*Child's Name*] in terms he/she could understand and confirm that he/she freely assented to take part in this study.

For children <u>unable</u> to assent:

I certify that _____ [*Child's Name*] was not capable of understanding the procedures involved in the study sufficiently to assent to study participation.

Name of Person Obtaining Assent

Signature of Person Obtaining Assent Date

If "NO": thank the individual for his/her time and end the call.
If "YES": Good. The written consent form [*and assent form, as applicable*] should be arriving at your home in the next 7-10 days. Please read it over carefully, sign it, and return the original consent form [*and assent form, as applicable*] in the postage-paid envelope and keep a copy for your records. Thank you very much for your time.