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 an Interarterial or Intraconal or Intramural Course (AAOCA): Establishing a Multi-Institutional Registry

Principal Investigator: Dr. Christopher A. Caldarone

Version: Subject Who Turns 18 years of age

Hello, my name is _____. I am a study coordinator from the Division of Cardiovascular Surgery at The Hospital for Sick Children.

You and your parent(s)/guardian(s) have been participating in the registry for children and young adults with anomalous aortic origin or a coronary artery (or AAOCA). Now that you have turned 18 years old and are an adult, I need to obtain your permission for continuing in this research study. Is this a good time to talk to you?
If "YES" proceed," if "NO", make arrangements for a convenient time.

Your participation in this study is completely voluntary. This means that you 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.

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 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 decide to continue in this study, you will allow research staff within the hospital to review your medical records to obtain 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.

You will also allow specially trained personnel from the CHSS Data Center to contact you on a yearly basis throughout your life to ask you several questions regarding your 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 continue to send your medical record data confidentially and securely to the CHSS Data Center.

If you agree to continue your participation in the registry, the only additional requirements will be to answer several health-related questions once a year throughout your life. There will be no additional exams for this study. All exercise tests, echocardiograms and other forms of monitoring are performed as standard of care.

Participation in this study is voluntary; you do not have to take part in order to receive ongoing care. 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 otherwise entitled. Your current and future medical care 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 health information. Every effort will be made to protect your 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 is no direct benefit to you from participating in this study. The information collected by this study may contribute to the care of children and adults in the future who have your 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 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 in order to conduct this study. This includes information about you 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 care and people who oversee or evaluate research and care activities at The Hospital for Sick Children will be allowed to access your 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. We will keep your 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 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 health information for this research.

The information collected as part of this study will be 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 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 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.

Financial Considerations
There is no charge or payment to you 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 rights and welfare are protected. You can talk to a person from this group if you have questions about your 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 keep you enrolled in this study? *(If "YES", proceed)*

_____
Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

_____
Name of Subject

If "NO": thank the individual for his/her time and end the call.
If "YES": Good. The written consent form 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 in the postage-paid envelope and keep a copy for your records. Thank you very much for your time.