Protocol Amendment Summary

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


SickKids* REB Approval: 12 Jan 2016

Revisions and Rationale for Changes:
Track Changes document
(changes made to current SickKids REB approved document, Version 3 – 29 Jun 2015)
Revisions to protocol to further detail/clarify current processes, and add process changes (e.g., addition of Questionnaires for annual follow-up); clarification with respect to consent process, to include authorization, as applicable; clarification of process to welcome subjects into study when they consent for themselves to continue participation; clarification with respect to obtaining consent for release of medical information; privacy section: further details provided with respect to the transfer of information to the CHSS Data Center; References: PedsQL references added; other minor administrative changes in text.

*SickKids = The Hospital for Sick Children, Toronto, Ontario, Canada