

## **Protocol Amendment Summary**

**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

**Protocol Version:** Version 3 – 29 Jun 2015

**SickKids\* REB Approval:** 14 Aug 2015 (signed 25 Aug 2015)

### **Revisions and Rationale for Changes:**

Protocol Version 3 – 29 Jun 2015

Track Changes document

(changes made to current SickKids REB approved document, Version 2 – 2009-09-21)

Revisions to protocol to further detail/clarify current processes , and add process changes (e.g., use of Consent for Release of Medical Information; use of CHSS Data Center Registration Form); added current process of welcoming parents/guardians of new subjects and new subjects enrolled into the study; Privacy, Security, Confidentiality sections reworded/updated for further clarity.

[Note: Protocol revisions initiated in response to Scientific Peer Review recommendations, include updates to the following sections of the Protocol: Follow-Up, Confidentiality. Scientific Peer Review approval was received on 30 Jun 2015, prior to submission of amendment to SickKids REB.]

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