

## **Protocol Amendment Summary**

**Study Title:** Atrioventricular Septal Defect – A Congenital Heart Surgeons’ Society Inception Cohort Study

**Protocol Version Date:** 16 Feb 2016

**SickKids\* REB Approval:** 12 May 2016

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

Protocol, Version Date: 16 Feb 2016

Track Changes document

(changes made to current SickKids REB approved document, Version Date: 2013-02-15)

Change in study title (removed ‘Unbalanced’) to reflect the study population included;

Revisions to protocol to identify Coordinating Investigator and Coordinating Site;

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; addition of

Questionnaires for annual follow-up); clarifications with respect to Echo Core Lab processes and

Echocardiography training; clarification with respect to consent process, to include authorization, as

applicable; added current process of welcoming parents/guardians of new subjects enrolled into the

study and provided clarification of process to welcome subjects into study when they consent for

themselves to continue participation; details provided with respect to subject completion/withdrawal;

further clarity provided for Inclusion/Exclusion Criteria; further clarity provided with respect to Clinical

Documents and Studies (including timing of Echos); Study Administration section added and further

details provided with respect to Data Collection and Management (including Privacy, Security and De-

identification), Confidentiality, and Regulatory and Ethical Considerations;

References: PedsQL™ references added and corrections made in References section;

other minor administrative changes in text.

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