

## **Protocol Amendment Summary**

**Study Title:** Congenital Heart Surgeons' Society Studies in Congenital Heart Disease

**Protocol Version Date:** 22 Sep 2015

**SickKids\* REB Approval:** 06 Jan 2016

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

Protocol – CHSS Studies in Congenital Heart Disease, Version Date: 22 Sep 2015

Track Changes document

(changes made to current SickKids REB approved document, Version Date: 2013 10 23)

Revisions to protocol to clarify that this is the protocol for the non-enrolling CHSS study cohorts (closed to enrollment), that are in follow-up phase only (see separate Appendices, addressing details of each of these cohorts); 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, including the role of the CHSS Data Center with respect to the consent process; clarification with respect to obtaining consent for release of medical information; confidentiality section: further details provided with respect to the current processes, including 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