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