Protocol Amendment Summary

Study Title: Tricuspid Atresia Study

Protocol Version Date: 22 Sep 2015

SickKids* REB Approval: 06 Jan 2016

Revisions and Rationale for Changes:
Track Changes document
(changes made to current SickKids REB approved document, Version Date: 01 Jul 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.

Special Consideration:
Per SickKids REB, the Tricuspid Atresia Study is covered under the umbrella study title ‘Congenital Heart
Surgeons’ Society Studies in Congenital Heart Disease’. The umbrella study also includes the CHSS non-
enrolling (closed to enrollment) study cohorts.

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