

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:

Protocol – Tricuspid Atresia Study, Version Date: 22 Sep 2015

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