

## **Protocol Amendment Summary**

**Study Title:** Tricuspid Atresia Study

**Protocol Version Date:** 01 Jul 2015

**SickKids\* REB Approval:** 14 Aug 2015 (signed 14 Aug 2015)

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

Protocol [Tricuspid Atresia Study], Version Date: 01 Jul 2015

Track Changes document

(changes made to Version Date: 08 June 2015 document, after SickKids Scientific Peer Review):

protocol was updated to include the process of welcoming newly enrolled, CHSS registered participants; revisions in statistical considerations section

[the Protocol (specifically for Tricuspid Atresia), Version Date: 08 June 2015, was newly created in response to Scientific Peer Review: Protocol was created to describe our current processes, and contains the essential elements per standard protocol requirements in observational research]

[Note: Scientific Peer Review (of Tricuspid Atresia Study) approval was received on 01 Jul 2015, prior to submission of amendment to SickKids REB.]

### **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