Protocol Amendment Summary

Study Title: Optimal Management of Critical Left Ventricular Outflow Tract Obstruction: A Congenital Heart Surgeons’ Society Study

Protocol Version Date: 22 Sep 2015

SickKids* REB Approval: 12 Jan 2016

Revisions and Rationale for Changes:
Research Protocol, Version Date: 22 Sep 2015
Track Changes document
(changes made to current SickKids REB approved document, Version Date: 30 Jun 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; confidentiality and security 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.

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