

Protocol Amendment Summary

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

Protocol Version Date: 30 Jun 2015

SickKids* REB Approval: 19 Aug 2015 (signed 25 Aug 2015)

Revisions and Rationale for Changes:

Research Protocol, Version Date: 30 Jun 2015

Track Changes document

(changes made to current SickKids REB approved document – undated (submitted to SickKids REB on 15 Dec 2004)

Revisions to protocol to further detail/clarify current processes , and add process changes (e.g., use of Consent for Release of Medical Information; use of CHSS Data Center Registration Form); now including waiver/alteration to include deceased subjects; added current process of welcoming parents/guardians of new subjects enrolled into the study; Confidentiality and Security section added to further detail processes; Risk Assessment section added; Statistical Analysis section revised; Publications section added.

[Note: Protocol revisions initiated in response to Scientific Peer Review recommendations, include updates to the following sections of the Protocol: Background, Study Population, Study Design, Follow-up, Outcomes/Follow-up and Statistical Analysis. Scientific Peer Review approval was received on 30 Jun 2015, prior to submission of amendment to SickKids REB.]

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