

Research Ethics Board (REB) Renewal Approval Letter

2018-01-23

Dr. Christopher Caldarone
Surgery - Cardiovascular Surgery

REB number: 1000028988

Study title: Atrioventricular Septal Defect - A Congenital Heart Surgeons' Society Inception Cohort Study

Date of initial study approval: 2012-01-09

Study expiry date: 2019-01-23

Thank you for your renewal application requesting a renewal and approval of the above named study.

This letter will serve as an extension of the SickKids Research Ethics Board (REB) approval for the study. This renewal was approved by the REB via delegated review (not by Full Board review). This approval is effective from **2018-01-23** to **2019-01-23**. Continuation beyond that date will require further review of REB approval.

During the course of this investigation, any significant deviations from the approved protocol and/or unanticipated developments or significant adverse events should immediately be brought to the attention of the REB.



Elizabeth A. Stephenson, M.D., MSc.
REB Chair

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The SickKids REB operates in compliance with the Tri-Council Policy Statement; ICH Guideline for Good Clinical Practice E6(R1); Ontario Personal Health Information Protection Act (2004); Part C Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations and the Medical Devices Regulations of Health Canada. The approval and the views of the REB have been documented in writing. The REB has reviewed and approved the clinical trial protocol and informed consent form for the trial. All investigational drug trials at SickKids are conducted by qualified investigators.

Furthermore, members of the Research Ethics Board who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.