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Dear CHSS members,

Please find attached a group of forms pertaining to the Critical Left Ventricular Outflow Tract Obstruction Study (LVOTO). The protocol has been approved by the Ethics Board at the Hospital for Sick Children and the forms may be useful for application to the Ethics Board in each member institution. An application form, consent form, and protocol form are included for your review. In addition, a patient enrollment form is included which summarizes the enrollment process in convenient .pdf format.

The Critical LVOTO study is important for two reasons:

First, it will enroll a prospective cohort of neonates across the entire range of single ventricle management strategies including transplantation and pulmonary artery banding/ductal stenting (hybrid) procedures in addition to the Norwood (RV-PA conduit and aortopulmonary shunt) subtypes. In addition, neonates dying prior to any surgical intervention will also be enrolled. Consequently, the study will allow a comprehensive cross section analysis of ALL current single ventricle management strategies. This will be a timely analysis due to recent advances in postoperative Norwood management (e.g. afterload reduction, RV-PA shunts), transplantation (e.g. ABO incompatible), and the emergence of hybrid strategies. These recent advances accentuate the importance of this study to define optimum strategies based on evolving currently available techniques. In addition, the continuous follow up of the cohort will allow long term analysis of these management strategies through the transition states to Fontan, re-transplantation, as well as evaluation of crossovers to transplantation.

Second, after conducting a thorough analysis of outcomes after single ventricle repair strategies (noted above) and biventricular repair strategies (e.g. rastelli-type and Ross-Konno type procedures), the study will allow refinement of statistical tools to assist in decision making between single and biventricular repairs. The entry criteria are designed to capture the large group of patients in the 'grey zone' where choosing the optimal strategy is difficult. The previously published calculator (Lofland et al) will be refined with modeling of current outcomes and inclusion of more detailed preoperative morphologic and physiologic data.

We intend for this study to serve as a foundation for subsequent studies evaluating a variety of clinical questions. For example, comparison of quality of life endpoints in survivors of single ventricle and biventricular repair may be performed.

In order to facilitate this protocol, it is important to note that the amount of data requested on a per-patient basis is greater than in previous studies. Consequently, a concerted effort will be made to raise funds to offset the burden to individual institutions. Marshal Jacobs has demonstrated that this can be done with his funding for the pulmonary conduit study and we will follow his lead to acquire funding for this trial. We will keep you updated as to progress in this effort.

Sincerely
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Bill Williams
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