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SUBJECT INFORMATION AND CONSENT FORM

Title of Study:

Cardiac preload indicators in children, evaluation of invasive and non-invasive markers of fluid responsiveness

Principal Investigator:

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1. INTRODUCTION

You are invited to have your child participate in this study because he/she is undergoing a procedure in the cardiac catheterization lab that requires a general anesthetic. We are investigating how normal changes in blood pressure and changes in light absorption in the fingers as measured with a pulse oximeter (measures the oxygen in the blood) can improve the safety of giving intravenous (IV – skinny plastic tube in the hand) fluids.

2. YOUR PARTICIPATION IS VOLUNTARY

Your child's participation is entirely voluntary, so it is up to you to decide whether or not to have your child participate. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to your child during the study and the possible benefits, risks and discomforts.

If you do decide to have your child participate, you will be asked to sign this form. You are still free to withdraw at any time and without giving any reasons for your decision.

If you choose not to be involved or to withdraw your child from the study, you do not have to tell us why. The medical care that your child will be receiving will not be any different or less than the care he/she would normally receive. Please take time to read this information and ask any questions that may help you understand the study before you decide whether to be in the study or not.

3. BACKGROUND

Your child is undergoing a procedure that requires general anesthesia with breathing assistance and special tubes to be inserted into the large vein and artery (blood vessels) of the leg. Your child's cardiologist and anesthesiologist will explain these procedures in detail to you. We are interested in examining a number of methods of monitoring the pressure in blood vessels in the leg and near the heart.

We are investigating three separate types of measurements. Firstly, the normal changes occurring in blood pressure while your child's breathing is being assisted. Secondly, we will examine the changes in the signal from another routine monitor, the pulse oximeter (a sticker that usually goes around the finger) which measures oxygen content in the blood using red light. Finally, we will examine the pressure in two blood vessels near the heart (the vena cava and pulmonary arteries) that are used to assess the heart's function.

The variations in blood pressure that occur while breathing is assisted are used in adult patients to guide treatment decisions. This variation, called pulse pressure variation (PPV) can help to direct the amount of IV fluid given to a patient while under anesthesia or while unwell. It is uncertain whether this evidence applies to children. The aims of this study are to increase the information we can get from simple monitoring devices and explore how these changes in pressure and light absorbency can help doctors predict the need for IV fluid to be given to children.

We are planning to recruit 20 children at BC Children's Hospital.

4. WHY IS THIS STUDY BEING DONE?

The idea behind this study is to allow us to be able to get information from the pulse oximeter and from the blood pressure that up to now has only been available by monitoring blood vessels near the heart; allowing us to more safely monitor and administer fluid to children under anesthesia or who are unwell.

5. WHO CAN PARTICIPATE IN THE STUDY?

In order to participate in the study, your child must be aged from birth-18 years, undergoing one of these procedures in the cardiac catheterization lab: atrial septal defect (ASD) repair or patent ductus arteriosus (PDA) repair, or balloon valvuloplasty of pulmonary/aortic valve stenosis. They must also have had a previous echocardiogram examination.

6. WHO SHOULD NOT PARTICIPATE IN THE STUDY?

Children with any other heart abnormalities cannot participate, as this is likely to make the results unreliable. Children who have disturbances in heart rhythm (e.g. atrial fibrillation, atrio-ventricular block) cannot participate as these disturbances do not allow us to calculate the necessary changes in blood pressure accurately. Children with special lung or kidney problems also cannot participate. Your child's anesthetist will be able to tell you if your child is eligible.

7. WHAT DOES THE STUDY INVOLVE?

Your child will be anesthetized as usual and will have all the usual monitors placed. No change shall be made to the anesthetic given to your child. Once your child is asleep, two extra pulse oximeter probes (similar to band-aid stickers) shall be placed onto the middle and ring fingers of one of your child's hands, and the probe covered with lightproof cloth. These probes just sit on the surface of the skin, and are identical in function to the probe your child will have as part of the standard monitoring.

Once these probes are placed and are working satisfactorily, data will be recorded from each, and from the monitor, which displays your child's vital signs during the operation, the anesthetic and repair procedure will not be changed and will proceed as normal.

Following the completion of the repair, data will be recorded from the monitor and the cardiologist will measure two pressures (right atrial pressure (RAP) and pulmonary capillary wedge pressure (PCWP)) from the heart followed by the pumping ability of the heart (cardiac output). This is done using a tube (thermodilution pulmonary artery catheter) placed in the same way as one during the repair procedure. This catheter is placed through a sheath which is

used during the repair so no extra needle is needed. At this point your child will be given some IV fluids. Once this fluid has been given, the recordings from the monitor and the heart will be repeated. At this point, the study will be completed and the procedure and anesthetic will be completed as normal.

There are no extra needles and/or medications given to your child.

If your child does not take part in the study, he/she will not have the extra pulse oximeter probes or a thermodilution pulmonary artery catheter placed for study purposes (they may need to have one placed as part of the repair) or have data recorded. However, the anesthetic medicines received, IV fluids, and the repair procedure will be identical.

8. WHAT ARE THE POSSIBLE HARMS AND SIDE EFFECTS OF PARTICIPATING?

The procedures that are specific to the study and their risks are as follows:

- i. Two extra pulse oximeter probes placed on the fingers for the duration of the procedure have no associated risks.
- ii. Thermodilution pulmonary arterial catheter (PAC) placement, measurement of PCWP and cardiac output. Multiple catheter changes are routine during the repair procedure. The additional risks due to PAC placement include: serious disturbance of heart rhythm, knotting of the catheter or damage to the heart. These complications are extremely rare (less than 1 in 2000) and add almost no risk to the repair procedure.
- iii. There will be an increased duration of anesthesia of about 25% due to the study; this means an increase from around 2 hours to around 2.5 hours. The additional risk is minimal as almost all anesthetic risk is associated with going to sleep and waking from anesthesia.
- iv. There will be a short increase in the exposure of your child to x-rays. Children are exposed to x-rays as a standard part of the repair for up to 15 minutes. This will be increased by 30-60 seconds or 5%.

9. WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

Your child will not directly benefit from participation in this study. The information we get from this study will be used in the formulation of further studies, the aim of which is the safer administration of IV fluids to children under anesthesia or those who are unwell.

10. WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

Your child's participation in this research is entirely voluntary. You may withdraw your child from this study at any time. If you decide to enter your child in the study and withdraw at any time in the future, there will be no penalty or loss of benefits to which you and your child are otherwise entitled, and your child's future medical care will not be affected.

If you choose to enter the study and then decide to withdraw at a later time, all data collected about your child during his/her enrolment in the study will be retained for analysis. By law, this data cannot be destroyed.

11. WHAT HAPPENS IF SOMETHING GOES WRONG?

By signing this consent form you are in no way waiving your or your child's legal rights or releasing the investigator or anyone else from their legal and professional responsibilities.

12. CAN MY CHILD BE ASKED TO LEAVE THE STUDY?

The study doctor(s)/investigators may decide to discontinue the study at any time, or withdraw your child from the study at any time, if they feel that it is in your child's best interests.

13. WHAT WILL THE STUDY COST ME?

There will be no additional cost to you for your child's participation in the study. You will not be charged for any research procedure. You or your child will not receive any remuneration/reimbursement for participation.

14. WILL MY CHILD'S PARTICIPATION IN THIS STUDY BE KEPT CONFIDENTIAL?

Your child's confidentiality will be respected. No information that discloses your child's identity will be released or published without your specific consent to the disclosure.

Research records and medical records identifying your child may be inspected, in the presence of an Investigator or his or her designate, by representatives of the UBC Research Ethics Board, for the purpose of monitoring the research. However, records which identify your child by name or initials will be kept in a locked cabinet and will not be allowed to leave the Investigators' offices. Copies of relevant data, which identify your child only by unique code number, may be required by regulatory agencies. However, your child will not be identified by name, initials, or date of birth as part of this study data.

15. WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY CHILD'S PARTICIPATION?

If you have any questions or desire further information about this study before or during your child's participation, you can contact Dr. Norbert Froese at 604-875-2711.

16. WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY CHILD'S RIGHTS AS A SUBJECT DURING THE STUDY?

If you have any concerns about your child's treatment rights as a research subject, please contact the Research Subject Information Line at the University of British Columbia Office of Research Services at 604-822-8598.

16. CONSENT TO PARTICIPATE

I have read or have had read to me all of the above. I have had enough time to consider entry to the study. All of my questions have been answered to my satisfaction. I understand that my child's participation is entirely voluntary and that he/she may refuse to participate, or I may withdraw my child from the study at any time.

The parent(s)/guardian(s) and the investigator are satisfied that the information contained in this consent form was explained to the child to the extent that he/she is able to understand it, that all questions have been answered, and that the child assents to participating in the research.

I acknowledge I will receive a signed and dated copy of this consent form for my own records.

Name of Subject: _____

Printed name of subject's parent / Legally acceptable representative	Signature	Date
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Printed name of principal investigator/ designated representative	Signature	Date
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Printed name of translator	Signature	Date
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SUBJECT'S ASSENT TO PARTICIPATE IN RESEARCH

I have had the opportunity to read this consent form, to ask questions about my participation in this research, and to discuss my participation with my parents/guardians. All my questions have been answered. I understand that I may withdraw from this research at any time, and that this will not interfere with the availability to me of other health care. I have received a copy of this consent form. I assent to participate in this study.

Printed name of subject

Signature

Date