



# CHILDREN'S & WOMEN'S HEALTH CENTRE OF BRITISH COLUMBIA

*Department of Anesthesiology  
British Columbia's Children Hospital  
4480 Oak Street  
Vancouver  
V6H 3V4  
Tel 604 875 2711  
Fax 604 875 3221*

## **SUBJECT INFORMATION AND CONSENT FORM**

Title of Study:

Post cardiac surgery blood loss: Effect of washing residual cardiopulmonary bypass circuit blood red cells prior to re-infusion.

**Principal Investigator:**

Dr. Norbert Froese  
Department of Anesthesia  
BC Children's Hospital  
Telephone: 604-875-2711

**24-hr Emergency Telephone Number:**

604-875-2161  
Ask to page the anesthesiologist on call.

**Co-Investigators:**

Andrew Campbell  
Pascal Lavoie  
Jacques Leblanc  
Doug Salt  
John Wu

## **INTRODUCTION**

You are invited to have your child participate in this study because he/she is undergoing a procedure that requires a heart lung machine to keep blood flowing while your child's own heart is stopped. After unhooking the heart lung machine, there is a lot of residual blood left in it. This blood is routinely returned to your child after the surgery is over. We are investigating whether or not washing the red cells before they are returned to your child will improve the ability of your child's blood to clot and lead to less blood loss after surgery.

## **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.

## **BACKGROUND**

When a child undergoes heart surgery, a heart lung machine is used to keep blood flowing while the child's own heart is stopped. After surgery, a significant amount of the child's own blood is left in this machine.

In your child's surgery, his/her doctors will try to give all this blood back after the operation. Giving your child back his or her own blood makes it less likely that your child will need a transfusion of donated blood.

However, we know that giving your child back this blood can sometimes make it more difficult for your child's blood to clot, and can sometimes cause an increase in blood lost **through** bleeding after surgery.

This project will explore the effects of returning only the red blood cells left in the heart lung machine to children. This is done by using a method that involves separating the red cells from the rest of the blood, washing the red cells, and returning only the red cells to the child.

## **WHY IS THIS STUDY BEING DONE?**

This study is being done so we can learn the exact reasons why some children's blood clots less well after their heart lung machine blood is given back to them. This study will also find out if washing the red cells left in the heart lung machine before they are given back to the child will be better for the child's clotting system.

**There are also advantages with minimizing transfusion to children (e.g. decreased risks for kids, decreased costs and burdens on the already stressed blood collection, processing and distribution system).**

## **WHO CAN PARTICIPATE IN THE STUDY?**

In order to participate your child must be between 2 and 10 years of age and between 15 and 30 kg undergoing heart surgery requiring cardiopulmonary bypass at British Columbia Children's Hospital. Only those children **whose** surgery is of the type where all the heart lung machine blood is normally given back to them will be invited to participate in this study.

## **WHO SHOULD NOT PARTICIPATE IN THE STUDY?**

Children who have a problem with blood clotting should not participate in this study.

## **WHAT DOES THE STUDY INVOLVE?**

If your child qualifies to be included in this study, and you agree to allow him/her participate, he/she will be assigned to one of two groups by chance (like roll of dice). One group is the "normal current practice" group, and the other group is the "washed red

cell” group. The difference between the groups is what happens to the blood left in the heart lung machine before it is returned to your child.

If your child is assigned to the “normal current practice” group, the blood left in the heart lung machine will have as much water removed from it as possible with a special blood filter. This blood will then be returned to your child over the next **1 hour**. Because this blood has been treated with heparin, which is a medication which prevents the blood from clotting in the heart lung machine, your child will be given a medicine called protamine while this blood is returned. The protamine will reverse the effects of the heparin on blood clotting. The procedures just described for the “normal current practice” group are how we currently return the blood left in the heart lung machine to children such as yours undergoing heart surgery.

If your child is assigned to the “washed red cells” group, the red cells in the blood left in the heart lung machine will be separated from the remainder of the blood, and washed with a balanced salt solution. This procedure is commonly used to treat blood cells lost during many kinds of surgery before it is returned to patients. Your child’s red cells, floating in a balanced salt solution will then be returned to your child over the next **1 hour**. Because there is little heparin left in the washed red cells floated in a balanced salt solution there is no need to give protamine while they are returned.

All children in the study will have some blood sent for testing over and above what is usually done. None of these blood tests will require any additional needle pokes. All children having heart surgery have a catheter (skinny plastic straw-like tube), like an intravenous catheter, placed in an artery after they are asleep. This catheter is used to measure blood pressure, and is also used to take blood for blood tests both during surgery and after surgery while the child is in the intensive care unit. After this arterial catheter has been placed, at the same time as all children have blood taken for other tests, children in the study will have approximately 1/5<sup>th</sup> of a teaspoon of blood taken to measure how much hemoglobin is in their blood before the surgery starts. Children in the study will also have approximately one tablespoon of blood taken for detailed analysis of the clotting system, once before and once after they have been given back the blood left in the heart lung machine.

A sample of the blood left in the heart lung machine will be taken for testing before this blood is returned to your child.

Apart from the procedures described above, all care and procedures for children participating in the study will not be different from the care normally given to all children.

#### **WHAT ARE THE POSSIBLE HARMS AND SIDE EFFECTS OF PARTICIPATING?**

**If your child is assigned to the “normal current practice” group, no additional risks related to the return of the blood left in the heart lung machine, over those encountered in normal practice, will occur. Although returning the blood left in the heart lung machine can make it more difficult for your child's blood to clot and can lead to increased bleeding after surgery, returning this blood is normal current practice at our hospital because returning this blood to your child decreases the chances that donated blood products that will have to be administered to your child.**

**If your child is assigned to the “washed red cells” group, the blood left in the heart lung machine will undergo additional processing before being returned to**

**your child. This processing is commonly used in other operations where significant amount of blood is lost. A small percentage of the red cells in the residual pump blood will be lost during this processing. All components of blood other than the red cells, including platelets and clotting factors, are removed during this processing. Current data suggests that removing these other components will not increase the risks of bleeding after surgery, nor will it increase the risk of your child requiring blood product transfusion.**

**We believe for this study that the children assigned to the “washed red cells” group, the returning of washed leftover blood will have less bad effects on the blood clotting system and will result in less blood loss after surgery.**

#### **WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?**

Your child will not directly benefit from participation in this study. The knowledge gained through this study will be used to improve the safety of returning blood left in the heart lung machine to children.

#### **WHAT ARE THE ALTERNATIVES TO THE STUDY TREATMENT?**

**If not enrolled in the study, your child will have as much of the residual blood in the heart lung machine return to him/her in an effort to decrease the chances of needing to transfuse donated blood product. Washing the red cells before returning them is not currently practiced except as part of this study.**

#### **WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?**

You will be notified immediately of any new information as soon as we have this available.

#### **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.

#### **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.

#### **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.

**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.

**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 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.

**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. Froese at 604-875-2711.

**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.

**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 having received 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

\_\_\_\_\_  
Printed name of witness                      Signature                      Date

\_\_\_\_\_  
Printed name of principal investigator/ Designated representative                      Signature                      Date