INFORMATION FOR FAMILIES / FRIENDS

Study of Whole Blood in Frontline Trauma in Aotearoa: A Randomized Controlled Feasibility Trial Assessing Prehospital Platelet-Rich Whole Blood versus Platelet-Poor Whole Blood in Traumatic Haemorrhage

Short Title: SWiFT Aotearoa

Principal Investigator:	Dr Richard Charlewood & Dr Alana Harper
Clinical Site:	Northern Rescue Helicopter
Sponsor:	New Zealand Blood Service

Thank you for taking the time to talk to us about the **SWiFT Aotearoa** Study.

We appreciate that right now everything may be overwhelming and there is a lot of information to take in. The following information tells you about the study and you can read through this at your own pace.

Please ask as many questions as you need to so that you understand what is happening and make notes on this document to remind you to ask something that may come up later. When you have finished reading this information sheet, please take a moment to consider what your family member / friend may want to happen under these circumstances.

What the study is about and what it involves: The reason your friend/family member is considered eligible for the **SWiFT Aotearoa** Study is because they have a severe injury and had lost a lot of blood.

Blood is important to move oxygen and nutrients around the body and remove waste products. The pre-hospital doctors and paramedics agreed a blood transfusion was required before arriving at the hospital.

The **SWiFT Aotearoa study** is looking at two different types of blood transfusion with patients receiving either the “**control treatment**” and the “**investigational treatment**”. Patients will be randomly assigned treatment.

The **control treatment** is the standard of care blood patients in New Zealand would typically get when a blood transfusion is given, platelet-poor whole blood. This is red blood cells and plasma. The **investigational treatment** is the standard of care blood, with the addition of platelets, called platelet-rich whole blood. Platelets help with blood clotting and are normally given at the hospital. This is because platelets are difficult to carry in the air ambulance. Platelet-rich whole blood is standard of care in countries like the United States.

Giving a blood transfusion of red blood cells, plasma and platelets all at once could improve patient outcomes and recovery. The platelets may improve clotting, decreasing the number and volume of additional blood transfusions. However this is not fully known.

The study is looking to see which of the transfusion types is better (or whether there is no difference between them) so that more patients in the future will get the best treatment.

After the blood transfusion is given, we plan to follow your friend/family member for 90 days. We will see them while they are in hospital and check their medical notes at set time points through to 90 days to see how things are going. We don’t ask them to do anything extra for the follow-up, the information we collect is standard of care.

Consent is an integral part of research; we would normally ask a person if they give their permission to be involved in a study. We explain the study, why we are doing it, the benefits and any risks, as well as the fact that research is voluntary. We realised that patients who have had a severe injury and had lost a lot of blood may not be able to provide their own informed consent. With this in mind, we have asked the NZ Health and Disability Ethics committee to allow the research team to include patients in this trial when participation will be in their **"Best Interest"**.

This means the decision to include your friend/family member in this study will be made by the treating doctor and paramedic, taking into account the known wishes of the patient, the requirements of the study and whether involvement would be in the Best Interest of the patient.

The doctor and paramedic make every attempt to talk to families and friends, so that we know how the family/friends feel about the study, and what the family/friends believe the patient would have wanted to happen. Sometimes though, this is not possible before we give a blood transfusion. In this instance we document that no discussion occurred and that we will discuss this with you as soon as possible.

If the doctor and paramedic agree that involvement in the study is in the Best Interest of the patient, it will be documented in the "Best Interest Statement". This agreement and your views, if available, will also be documented in the clinical notes. If the doctor and/or paramedic, and/or you, feel that this is not the right thing to do at this time, we will not go ahead with involvement in the study and will follow the normal standard of care. Once, the patient can work through the information themselves, we will ask their permission to continue with follow-up.

Thank you again for taking the time to talk us, we know that this can be a very stressful time.

Please feel free to use the space below to write down any questions you may think of.

This section is to be completed by family member / friend:

I acknowledge I am **NOT** providing consent for my family member / friend to be part of the SWiFT Aotearoa study and that I have been asked by the medical team to help them understand the wishes (name of patient) ______________________________.

To the best of my knowledge, I believe (the patient would have ***agreed / not agreed / I do not know***, to participate in the SWiFT Aotearoa study, had they been able to participate in the decision-making process themselves.

Family member / friends name: ____

Relationship: ________________________________

Signature: ________________________________ Date: ____________________

(dd/mm/yy)

This section is to be completed by the Investigator:

I have given a verbal explanation of the SWiFT Aotearoa study to the family member / friend of (name of patient)_______________________________, and have answered any questions about it.

Investigator's name: ____

Signature: ________________________________ Date: ____________Time: ______

(dd/mm/yy) **(hh:mm)**

Interpreter's Name	**Signature**	**Date**