



[NHS TRUST LOGO]

Professional Legal Representative Information Sheet

Title of Study:	A Multi-Centre Randomised Controlled Trial of Pre-Hospital Whole Blood Administration versus Standard Blood Component Care for Traumatic Haemorrhage.
Chief Investigators:	Dr Laura Green and Professor Jason Smith
Sponsor:	NHS Blood and Transplant (NHSBT)

Introduction

This hospital is taking part in a research study to investigate different types of blood transfusion given to patients who are bleeding after suffering a serious injury.

About the study

This study is investigating different blood transfusion treatments for patients with severe bleeding before they get to hospital. Any delay to starting transfusion can reduce the chances of survival.

UK air ambulances treat patients with a combination of red blood cells and plasma, which come in separate bags. Platelets are only given after arrival at hospital. Carrying separate blood component bags has logistical challenges (additional weight, and several bags may need to be given leading to a potential delay to hospital).

In this study, one group of patients will be given transfusions of red blood cells and plasma. The other group of patients will receive transfusions of whole blood (red blood cells, plasma, and platelets all in one bag). The effects of the two different treatments will be compared by looking at survival in the two groups and the amount of blood needed over the first 24 hours after injury. We are also investigating how the patients are doing up to three months after their injury.

At the end of the study we will determine 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.

Why am I being given this information?

As your patient's treatment was an emergency, the attending Doctor was not able to discuss the study with your patient, their parents / guardians, relatives or friends in advance.

Because of this, they were enrolled into the study by the Air Ambulance Doctor who treated them at the scene under an 'Emergency waiver of consent'.

You have been asked to provide Professional Legal Representative consent for this patient to remain in the study. We hope that this will only be until your patient or their relatives, friends or parents / guardian have been contacted by the research team about their continuing participation in the study.

What am I agreeing to?

Until your patient or their relatives, friends or parents/guardians have been contacted by the research team, you are agreeing to:

- Allow us to collect routine clinical information about your patient, the care they receive whilst they are in hospital and after they are discharged.
- Contact them to ask them to complete a questionnaire about their health 90 days after their injury.
- To contact their GP to find out about their health in 90 days if we cannot contact them directly.

We will also use their identifiable data to collect information about their injuries and treatment from secondary care, Trauma Audit and Research Network (TARN) and the Intensive Care National Audit & Research Centre (ICNARC).

What are the possible risks and benefits to my patient of taking part?

There are no known risks linked to/attribution to taking part in this study, and there are no known additional risks in participating in the study compared to the risk associated with transfusing standard blood components.

However, information collected as part of their participation in this trial may benefit patients in the future, even if they were randomly allocated to the standard treatment group.

Who is organising the research and who has reviewed it?

The study is being managed by NHS Blood and Transplant Clinical Trials Unit. The study has been funded by NHS Blood and Transplant, the Ministry of Defence and ten different Air Ambulance Services. This study has been approved by the South Central – Oxford C Research Ethics Committee and the Health Research Authority.

The Sponsor has insurance under the Clinical Negligence Scheme for Trusts. In the unlikely event that something does go wrong and your patient is harmed during the research due to negligence then they may have grounds for a legal action for compensation against the NHS Trust, but they may have to pay legal costs. The normal National Health Service complaints mechanisms will still be available to them (if appropriate).

How will my information be used?

Your NHS Trust will keep the form you sign, which includes your name, signature and role. It will not be sent to any third parties. It will not be recorded on the study database. Everyone involved in this study will keep your data safe and secure. We will follow all privacy rules.

The Sponsor or regulatory authorities can view your information at your Trust to make sure that the research is being done properly.

Your NHS Trust will archive the consent forms at the end of the trial. It will be kept for 15 years, after which time it will be destroyed.

Who should I contact for further information?

If you have questions or concerns you can contact the local Principal Investigator or Research Nurse, who is in charge of the research study at this hospital:

Principal Investigator	Research Nurse
[to be localised]	[to be localised]