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CRITICAL CARE MEDICINE,
Education & Research Centre,
St Vincent's University Hospital

Version 1, Dated 21 June 2013

PARTICIPANT INFORMATION AND CONSENT FORM

You are being invited to participate in a research study. Thank you for taking time to read this.

Full Project Title: A multi-centre randomised double blinded phase III trial of the effect of standard issue red blood cell blood units on mortality compared to freshest available red blood cell units **(TRANSFUSE Study)**

Principal Investigator:

Prof Alistair Nichol
Dr Derek Barton
Dr Andrew Westbrook

1. What is the purpose of this study?

The TRANSFUSE study is investigating whether Intensive Care patients will benefit from receiving the freshest compatible blood available from the blood bank, compared to the current standard practice which is to use the oldest compatible blood.

Almost all patients who require a blood transfusion during their Intensive Care stay will be included in the TRANSFUSE study. The study will enrol a total of 5000 patients and is also taking place in Australia, New Zealand, Finland and Ireland.

This study is being coordinated by the Australian and New Zealand Intensive Care research centre at Monash University, Melbourne, Australia and it is funded by the Australian Government.

2. What will happen if I volunteer?

When the decision is made by the Doctors that you require a blood transfusion you would be randomly (like tossing a coin to make a decision) assigned to receive either standard allocation blood or the freshest available blood throughout their hospital stay. If you decide that you will participate in the study then any future blood transfusions will continue as initially assigned.

The management and care of you will remain the same and there are no extra tests or procedures required. The researchers will collect some basic details about your illness and management. After you have been discharged from hospital the researchers will be in contact by telephone to check how you are recovering at 3 and 6 months. The 6 month phone call will also involve a simple questionnaire that measures quality of life. This should take no longer than 5 minutes to complete.

Information about your participation in this research project will be recorded in your health records.

Your health records and any information obtained during the study are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the coordinating centre, the ANZIC-Research Centre at Monash University, St.Vincent's University Hospital or as required by law. By signing the consent section, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

3. What is the possible benefit/risk with participating in the study?

There may be some benefit to patients who receive the freshest available blood during their hospital stay. There is no risk with participation in the study.

4. What happens is I do not agree to participate?

Participation in any research project is voluntary. If you do not wish to take part you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or the relationship with St.Vincent's University Hospital.

5. Confidentiality

Any information obtained in connection with this study that can identify you will remain confidential and will only be used for the purpose of this study. It will only be disclosed with your permission, except as required by law. Only the treating staff will know whether or not you are participating in this study. Research information will be collected by the research staff from your relative's medical record. This study information will be kept in a locked filing cabinet in the secure research office which is only accessible to the research staff. Your research information will be sent to the coordinating centre at the ANZIC-Research Centre at Monash University, Australia. This information will be provided to the coordinating centre in such a way that you cannot be identified. The research study results will be held securely at the coordinating centre. The study information, when destroyed, will be shredded or deleted.

We plan to discuss and publish the results from this study in peer-reviewed journals, conference presentations and other professional forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified. Only group results will be published and/or presented.

6. COMPENSATION

Your doctors are adequately insured by virtue of their participation in the clinical indemnity scheme.

7. WHO IS ORGANISING AND FUNDING THIS RESEARCH?

This study is organised by the Australian and New Zealand Intensive Care Research Centre and funded by the National Health and Medical Research Council of Australia.

You will not be paid for participating in this study.

8. Is this research project approved?

The Ethics and Medical Research Committee of St. Vincent's Healthcare Group has reviewed and approved this study.

This project will be carried out according to International Conference on Harmonization-Good Clinical Practice (ICH-GCP). This statement has been developed to protect the interests of people who agree to participate in human research studies.

9. Who can I contact?

Professor Alistair Nichol
Critical Care Medicine,
Education & Research Centre,
St Vincent's University Hospital.
Tel:– 01-2214218

PLEASE TICK YOUR RESPONSE IN THE APPROPRIATE BOX

- I have had the opportunity to ask questions and discuss the study YES ☐ NO ☐
- I have received satisfactory answers to all my questions YES ☐ NO ☐
- I have received enough information about this study YES ☐ NO ☐
- I understand that I am free to withdraw from the study at any time without giving a reason and without this affecting my future medical care YES ☐ NO ☐
- I agree to take part in the study YES ☐ NO ☐

Participant's Signature: _____ Date: _____

Participant's Name in print: _____

Investigator's Signature: _____ Date: _____

Investigator's Name in print: _____