

TESTING BLOOD DONOR CELL SURVIVAL FOLLOWING BLOOD TRANSFUSION**Invitation**

We are inviting you to participate in a research project called '*Testing blood donor cell survival following blood transfusion*' being conducted by Australian Red Cross Lifeblood (Lifeblood). The objective of this research project is to determine whether white blood cells (leucocytes) from blood donors can survive in patients who have had a blood transfusion. Even though all red blood cell units used for patient transfusions are filtered to remove donor leucocytes, some of the white blood cells may remain. This project aims to identify if any remaining donor cells survive after transfusion and to determine the effectiveness of Lifeblood's current processes.

You have been selected to participate in this research project because health data indicate that you may have had a blood transfusion in the past. If you have had a transfusion, you can provide a valuable blood sample to help confirm whether the filter processes prevent donor leucocytes being present during blood transfusion. If you have not had a transfusion or do not wish to participate you can disregard this letter or contact the 45 and Up Study on the Infoline (1300 45 11 45) or by email (45andUp@saxinstitute.org.au) to indicate this.

Participation in this research project is in addition to the main 45 and Up Study and your participation **is entirely optional, and your decision does not change your involvement in the main 45 and Up Study.**

To participate in this research project, we are asking you to provide blood samples to measure any surviving blood donor cells that may be present. Some of your blood samples will also become part of the 45 and Up Study Biobank and will be stored indefinitely. The biobanking samples may be used in additional health research that is in the public interest. Information from your blood sample will be stored securely in de-identified form, with access restricted only to authorised personnel.

We ask that you read this information sheet before deciding to participate in this research.

What is the purpose of the research project and who is involved?

The research project is looking to determine whether leucocytes from blood donors can survive in patients who have had a blood transfusion. Even though red blood cell units used for patient transfusions are filtered to remove these cells, this filter does not remove them all. The results from this research project will allow Lifeblood to determine how effective their current processes are.

It is being conducted by Dr Rena Hirani from the Research and Development department at Australian Red Cross Lifeblood. Recruitment to this project is being undertaken by the Sax Institute's 45 and Up Study.

Eligibility to donate

Bone marrow/stem cell transplant patients

If you may have had a bone marrow or stem cell transplant at any time, unfortunately we cannot accept your blood sample. This is because you received a number of different sources of cells and our tests will be unable to tell which came from the blood transfusion.

Pregnancy

Please note that at the time of blood collection, it is important that women participating are not currently pregnant, nor have previously been pregnant. It has been documented that cells from a foetus can be present in mothers following any pregnancy and this will make it hard to determine if the cells are from pregnancy or from blood transfusion. **If you have been pregnant, unfortunately we cannot accept your blood sample.**

What will happen in this research project?

If you agree to participate, you are asked to sign the Participant Consent Form (page 5). The consent form will be returned to the 45 and Up Study team. The Lifeblood researchers will not have access to your personal information.

If you do agree to participate, Lifeblood requires a single 3 mL (approximately half a teaspoon) blood sample. You will also be asked to provide an additional blood sample totalling 20 mL (approximately 1 tablespoon), that will be collected in 3 different tubes, for inclusion in the 45 and Up Study Biobank. These additional samples will be stored for future research.

The blood samples may be taken at your local pathology clinic (NSW Health Pathology, Douglas Hanly Moir or Laverty). There will be no cost to you.

The samples will be taken from the vein and will require a needle puncture.

Some of your research project blood sample will be tested for the presence of genetic information (markers). This will allow us to distinguish between your cells and any remaining blood donor cells. Your sample will not be screened for any genetic diseases, nor will any results obtained in this research project be diagnostic in any way. This means that any results obtained in this research project cannot be used by clinicians or other health professionals for any medical advice pertaining to you. All identifying information will be removed from your blood sample at the time of collection and no results from this research project can be provided back to you or your next of kin.

Lifeblood researchers will have access to deidentified health data including the date of any blood transfusion and the number of blood transfusions. This will be available as part of the 45 and Up information via your 45 and Up Study project-specific participant number. In the future, the 45 and Up Study may combine data from your blood sample with other information you have already allowed the 45 and Up Study to access, such as questionnaire responses and health and medical records. Any information about you will remain confidential and will be disclosed only with your permission or as required by law.

Do I have a choice?

Participation in this research project is voluntary. You are under no obligation to participate and a decision not to participate will not in any way affect any current or future relationships with Lifeblood or your involvement in the main 45 and Up Study.

You are free to withdraw from the research project for any reason until the blood sample has been drawn. After the sample has been taken the samples will have a reference number and the researchers will not be able to link you to your blood sample. For the research project, we cannot provide you with individual results as your sample will not be linked to you.

For the biobanking blood samples sent to the 45 and Up Study Biobank, you may withdraw blood samples at any time by contacting the 45 and Up Study team on the Infoline (1300 45 11 45) or by email (45andUp@saxinstitute.org.au).

If future research studies identify significant incidental findings from the biobanked samples, you will be contacted by the 45 and Up Study data custodian to discuss your options about receiving these results. If you elect to receive any incidental finding results from future research projects, then they will be provided via a genetic counsellor or otherwise qualified health professional.

What will happen to my blood samples after they have been used?

The blood sample for this research project will be held by Australian Red Cross Lifeblood at 17 O’Riordan St, Alexandria, NSW and will be destroyed following completion of the research. Information from your blood sample will be stored securely in de-identified form, with access restricted only to authorised personnel.

The blood samples collected for biobanking will be stored securely at the NSW Health Statewide Biobank at 67 Missenden Rd, Camperdown, NSW. These samples will become part of the 45 and Up Study Biobank to be stored indefinitely, and may be used in additional health-related research either nationally or internationally that is in the public interest and only after approval by an authorised Human Research Ethics Committee that meets Australian and internationally accepted ethical standards. Information from your blood samples will be stored securely in de-identified form, with access restricted only to authorised personnel.

Are there any risks?

There are no specific risks or side effects anticipated from participating in this research project beyond some minor discomfort associated with blood collection or minor bruising or swelling at the site where the blood sample is collected.

Are there any benefits?

We intend that this research project furthers medical knowledge and will provide valuable information on whether filtration procedures for blood products are effective in reducing long-term donor cell survival. Lifeblood will use the results from this research project to understand more about the current blood processing procedures and donor cell survival, and no information about you will be disclosed. There is no assurance that you will benefit from participation in this research project.

Will taking part in this research project cost me anything, and will I be paid?

Participation in this research project will not cost you anything nor will you be paid for participation. Blood sample collections will not result in any additional costs to you.

What happens with the results?

We plan to publish the results in scientific journals, conferences or at other professional forums. Internal reports may also be required for monitoring purposes. Individual participants will not be identifiable in any presentations or publication.

How will my privacy be protected?

Regarding your participation in the 45 and Up Study Biobank, your information is protected under the NSW Privacy and Personal Information Protection Act (1998) and the Health Records Information Privacy Act (2002) or international equivalent. The NSW Health Statewide Biobank, and Australian and international researchers accessing the Biobank must adhere to these laws, their ethics approval and policy.

Study Governance

The 45 and Up Study is owned and managed by the Sax Institute, in collaboration with major partner Cancer Council NSW; and partners: The Heart Foundation; NSW Ministry of Health; NSW Department of Communities and Justice; and Australian Red Cross Lifeblood.

Contact details and feedback

If you have any questions, please contact the 45 and Up Study on the Infoline (**1300 45 11 45**) or by email (**45andUp@saxinstitute.org.au**).

For details on the storage of blood samples, biospecimen data and the return of incidental findings, please refer to the NSW Statewide Biobank website (<https://biobank.health.nsw.gov.au/>).

This research project has been approved by Cancer Institute NSW Human Research Ethics Committee (HREC/16/CIPHS/4). If you have any concerns about the conduct of this project, or your rights as a participant, you may contact:

Executive Officer, Manager Research Ethics

Phone: (02) 8374 3610 or Email: CINSW-Ethics@health.nsw.gov.au

Thank you for taking the time to consider this research project. We could not conduct the 45 and Up Study without the generosity of our participants. We are immensely grateful to all of you.

If you wish to participate, please sign the enclosed consent form.

This information sheet is for you to keep.

CONSENT TO PARTICIPATE IN RESEARCH

PARTICIPATION IN THIS RESEARCH PROJECT IS OPTIONAL.

PLEASE READ THIS FORM AND SIGN IT IF YOU AGREE TO PARTICIPATE IN THE RESEARCH PROJECT "TESTING BLOOD DONOR CELL SURVIVAL FOLLOWING BLOOD TRANSFUSION" THAT IS BEING CONDUCTED BY AUSTRALIAN RED CROSS LIFEblood (LIFEblood) AND FOR BIOBANKING SAMPLES TO BE STORED BY THE 45 AND UP STUDY.

PLEASE PUT THE SIGNED FORM INTO THE 45 AND UP STUDY REPLY PAID ENVELOPE AND GIVE THIS TO THE BLOOD COLLECTOR TO SEND WITH YOUR BLOOD SAMPLES.

- I have read and understood that the research project will be conducted as described in the Information Statement, of which I have a copy.
 - I have been made aware of the procedures involved in the research project, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers; and that there is no assurance I will personally benefit from this research project
 - I understand that participation in this research project "TESTING BLOOD DONOR CELL SURVIVAL FOLLOWING BLOOD TRANSFUSION" involves providing blood samples for testing and no results from my blood sample will be given to me or my next of kin.
 - I understand that the research team may access information I have already given to the 45 and Up Study and other health records (clinical records, diagnosis history, pathology results, hospital and emergency department records) subject to authorised Human Research Ethics Committee review and I agree to this.
 - I understand that future 45 and Up Study research projects may link data from my blood sample with information I have already allowed the 45 and Up Study to access, such as questionnaire responses and health and medical records.
 - Researchers using this linked data will not be provided any identifying details (e.g. name and address)
 - I permit the long-term secure and anonymous storage of my blood or blood products, including DNA, which I donate to the research project and the 45 and Up Study, for use in health-related research either nationally or internationally that is approved by an authorised Human Research Ethics Committee that meets Australian and internationally accepted ethical standards and abides by Australian privacy laws.
 - I permit the NSW Health Statewide Biobank to store a copy of this consent form along with my blood samples.
 - I understand I can withdraw from the 45 and Up Study Biobank at any time without any effect on the healthcare I receive now, or in the future. My biospecimens and data held in the Biobank will be destroyed. I understand it will not be possible to withdraw my donated sample from the research project after donation as the researchers will not have any identifying information on my sample.
 - I understand that my personal information will remain confidential. Only non-identifiable data could be used for publications. For the biobanking samples, data may be used for other ethically approved research projects provided it cannot be identified back to me.
 - I have had the opportunity to have questions answered to my satisfaction.
 - If there are significant incidental findings from tests undertaken using my blood sample as a part of the 45 and Up Study Biobank-related research, I will be contacted to check if I would like these results unless I choose to opt out.
- I do not wish to be informed about any significant incidental findings from tests undertaken using my blood sample.**
- I hereby agree to participate in this research project and will allow the blood collection facility to take the required samples.

Participant name _____

Participant signature _____ Date _____