INFORMATION FOR PARTICIPANTS

Project Title	Centre for Personalised Immunology healthy blood donor scheme
ACT Health HREC Protocol Number	ETH.1.16.011
Chief Investigators	Professor Matthew Cook University of Cambridge Australian National University Matthew.Cook@anu.edu.au Phone: 02 5124 5586

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. What is the purpose of this study?

The immune system defends us against infection by bacteria, viruses and other micro-organisms. An important part of the immune system is white blood cells, which include lymphocytes, neutrophils, macrophages, and dendritic cells. We can identify and classify different white blood cells according to molecules expressed on their surface, their size and function.

We have established a substantial programme of research at the Centre for Personalised Immunology that aims to investigate how disease can result from abnormalities of white blood cells. This includes immune deficiency diseases, which result in increased risk of infection, autoimmune diseases such as lupus and Sjögren's syndrome, and severe inflammatory diseases, such as systemic vasculitis.

Most types of white blood cell types are accessible in the blood. From a sample of blood (a normal 'blood test'), we can purify different white blood cells in the laboratory for detailed analysis. In some cases, we can also freeze cells for future use. In other cases, however, cells do not survive this process and need to be analysed immediately.

In order to discover how the immune system goes wrong to cause disease, it is essential to compare the white blood cells from patients with those from healthy individuals. Indeed, there is considerable person-to-person variation in the function of healthy white blood cells, and so analysis of the blood from many healthy people is necessary for us to be confident about the significance of changes detected in patient samples.

We invite you as a healthy individual to enrol in a program to support our research by providing blood donations from time-to-time, which will be analysed as anonymous healthy control samples.

2. Why have I been invited to participate in this study?

You are eligible to participate in this study if you are healthy and do not have a personal or strong family history of immunological disease.

Certain exclusion criteria apply. You will not be able to take part in this study if you are on a medication that changes the function of your immune system (such as prednisone or an immunosuppressant), or if you have a medical condition that affects or arises from a problem with your immune system.

3. Eligibility

As this is a study of healthy people, you will be asked about aspects of your medical history at enrolment. Reasons that would prevent you from participation are as follows:

1. Known immunological disease: autoimmune disease such as lupus, rheumatoid arthritis, seronegative arthritis, type 1 diabetes, autoimmune thyroid disease, vasculitis, or immune deficiency.
2. Use of significant immune-modulating drug treatment, such as corticosteroids (prednisone), immunosuppressants (eg azathioprine or methotrexate), cytotoxic chemotherapy, radiotherapy, immune-modulating monoclonal antibody therapy (eg Etanercept)
3. First degree relative with confirmed systemic autoimmune disease or primary immune deficiency
4. Organ transplant
5. Cancer
6. Type 2 diabetes
7. Pregnancy
8. Known infection with HIV or Hepatitis C

4. What if I don't want to take part in this study or if I want to withdraw later?

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect any medical treatment you may seek or receive now or in the future. Whatever your decision, it will not affect your relationship with your health care team.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

You may withdraw from the study at any time and for any reason or no reason. Please tell the study team that you wish to withdraw from the study. Information that has been collected about you, prior to your

withdrawal, will continue to be used in the data analysis. No new information will be collected or used after you have withdrawn from the study.

5. What does this study involve?

This study will be conducted over approximately **five** years, but may extend beyond this time.

If you wish to volunteer as a research blood donor we will ask for your written consent and your contact details. Then we will collect some baseline information about you. This will include your full name, date of birth, sex, and ethnicity. We will also ask you some questions about your medical history to ensure you qualify as a healthy control for the purposes of this study.

The information we collect will be used to help us match control and patient samples for analysis.

You will be asked to donate up to 100mL of blood at any one time. For comparison, a normal blood test may draw between 30 and 40mL and a normal blood donation may draw as much as 450mL. We will ask you to consider donating blood samples no more often than every 3 months. The actual volume collected will be based on your age and weight. A standard health care calculation will be used to work how much blood we can take at a given time.

We will isolate white blood cells from your blood sample for analysis in the laboratory. The information obtained from analysis of healthy controls helps us interpret information obtained by similar analysis of patient samples.

Unless specified by you, we will also isolate DNA (genetic material) from your blood sample. Overall, our research is directed at understanding the genetic basis of immune disease. Sometimes, it is important to compare the frequency of gene variants in patients and healthy controls. The DNA isolated from your sample could be used for this purpose. As with the analysis of your white blood cells, the analysis would be performed on de-identified samples and we would not be able to either link the results back to you, or provide you with any results from these tests. If you wish, you can agree to provide just white blood cells but not DNA.

Once collected, blood samples are de-identified, coded, and processed anonymously. You will not receive any results from this study.

Your contact details will be maintained so we can contact you again and invite you to provide further samples. You can decline to provide more samples at any time. Indeed, you are at liberty to withdraw from the research at any time.

All data collected for the study will be maintained in a secure place and access will be restricted to chief investigators. No identifying information will be revealed should study results be published.

6. How will my blood samples be used?

Regulation states that samples may be used in a number of scenarios:

- Restricted – for the current study only

- Limited – for the current study and future similar studies (eg, studies looking at the same disease or condition)
- Unrestricted – for the current and any future studies

So that we can use your samples in a number of research studies we are asking for unrestricted use of the samples. This means we will be able to include your samples in any of our current or future research studies. All research studies, including future studies, will be subject to review and approval by an appropriately constituted Human Research Ethics Committee.

7. **How is this study being paid for?**

Our research is funded from various government and not-for-profit organisations. Our major support is from the National Health and Medical Research Council of Australia.

Your participation in this study will not cost you anything. Participants will not be paid for their involvement.

8. Are there risks to me in taking part in this study?

Blood tests may occasionally be painful and cause bruising. However, experienced staff will take your blood to minimise any discomfort. Occasionally, patients experience dizziness or fainting at the time of blood collection. Repeated blood donation can cause anaemia. Recent blood donation may affect your eligibility for blood donation at the Red Cross.

The research findings will not be of any direct benefit to you. However, they are likely to be of great benefit in offering insight in to mechanisms of disease of the immune system and may improve therapeutic choices of affected individuals.

9. **What if something goes wrong?**

If you suffer any injuries or complications as a result of your involvement in this study, you should contact the study team as soon as possible, who will assist you in arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

10. Who is organising and funding the research?

This research is funded by the National Health and Medical Research Council

No investigator or member of research staff will receive a personal financial benefit from your involvement in this study. The study doctors declare no personal conflict of interest relevant to the undertaking of this study.

11. How will my confidentiality be protected?

Of the people liaising with you, Professor Cook and the Clinical Liaison Officer, Ann-Maree Hatch will know the particulars of your participation in this study. Any identifiable information that is collected about you in connection with this study will remain separate from your samples and be kept confidential. No identifying information will be disclosed without your permission, except as required by law. Only the researchers named above will have access to your details and results that will be held securely at the Canberra Hospital and the Australian National University in a locked office within a secure, restricted access area.

12. What happens with the results?

Results will be published in the scientific literature. In any publication arising from this research, all information will be provided in such a way that you cannot be identified.

13. What should I do if I want to discuss this study further before I decide?

When you have read this information, the researcher liaison staff will discuss it with you and answer any queries you may have. You are also able to take this information away with you and discuss with your family, friends, treating doctor or any other person you choose. If you would like to know more at any stage, please do not hesitate to contact **Ann-Maree Hatch** on:

T: 02 5124 3272

Email: cpi.info@anu.edu.au

14. Who has reviewed this research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the ACT Health HREC.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	ACT Health HREC
HREC Executive Officer	August Marchesi
Telephone	02 5124 7968
Email	ethics@act.gov.au

Local Site Complaints contact person

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Name	Ann-Maree Hatch
Position	Clinical Liaison Officer
Telephone	02 5124 3272
Email	cpi.info@anu.edu.au

Thank you for taking the time to consider this study.
If you wish to take part, please sign the enclosed consent form.
This information sheet is for you to keep.

Consent Form to Participate in a Research Project (Adult)

Surname:	Given Name:
DOB:	Sex: ☐ Female ☐ Male
Address: Postcode	
Phone:	Email:

STATEMENT

I have been invited to enrol in a research project entitled**:**

Centre for Personalised Immunology healthy blood donor scheme

In relation to this project I have read the Information Sheet and have been informed of the following points:

1. Approval has been given by ACT Health Human Research Ethics Committee (HREC).

2. The aim of this project is to establish a registry of healthy blood donors from whom we will collect blood. These samples will be used to help us interpret results from patients with immunological disease.

   I understand I am providing samples for unrestricted future use as explained in the information sheet section 6.

3. The project will involve taking up to 100mL (approximately 5 tablespoons) of blood (or less if my body mass is less than 50kg). Repeat blood samples will be requested from time to time, but not more than 3 monthly.

4. Should I develop a problem which I suspect may have resulted from my involvement in this project, I am aware that I may contact –

   Dr Wei-I Lee – 02 5124 8523

5. Should I have any problems or queries about the way in which the study was conducted, and I do not feel comfortable contacting the research staff, I am aware that I may contact the Secretary of the ACT Health Human Research Ethics Committee, Ms August Marchesi on phone number 02-5124 7968.

6. I can refuse to take part in this project or withdraw from it at any time without prejudice. If I decide to withdraw from the study, my study records and results will not be analysed as part of the study from the time forward of my withdrawal.

7. Participation in this project will not result in any extra medical and/or hospital costs to me.

8. Results of my tests or information regarding my medical history will only be published after all data that could identify me has been removed.

9. ☐ I do not want to have my DNA (genetic material) analysed

I also state that I have/have not participated in any other research project in the past 3 months. If I have, the details are as follows:

_____

CONSENT

After considering all these points, I accept the invitation to enrol in this project.

_____	_____	_____
Name	Signature	Date
_____	_____	_____
Witness Name	Witness Signature	Date

INVESTIGATORS SIGNATURE

_____	_____	_____
Investigators Name	Investigators Signature	Date