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INFORMATION SHEET

Recruitment of volunteers for the study of genetic factors associated with chronic diseases

You are invited to take part in this study to help us to identify genes and lifestyle factors that may alter risk to a range of chronic diseases. The study has received ethical approval from the **Upper South A Ethics Committee**.

Investigators

Dr Rebecca Roberts, Research Fellow

Dr Richard Gearry, Gastroenterologist

Associate Professor Murray Barclay, Gastroenterologist

Dr Jeffrey Ngu, Gastroenterology Registrar

Dr Catherine Stedman, Gastroenterologist

Reasons for the Study

Many chronic diseases are rapidly increasing in Canterbury, and as a result are becoming a major health issue in our region and other parts of New Zealand. For the purpose of this study a chronic disease is a disease that can occur at any time in a person's life, can significantly affect the quality of life, and is often incurable. Examples of chronic diseases include rheumatoid arthritis, gout, inflammatory bowel disease, and type 1 diabetes. The cause of most of these diseases is unknown. What is known is the risk of developing a chronic disease is partly determined by a person's genes and partly by their lifestyle. The goal of this study is to identify these factors. If successful this study will help in the development of health strategies designed to better manage and prevent these diseases.

What does Participating Involve?

Your participation in the study is entirely voluntary.

This study involves

- Completing a questionnaire so we are able to collect demographic, medical and lifestyle information
- Providing 15mL of blood for DNA
- Providing 20mL of urine for measurement of uric acid and other compounds
- Agreeing to your DNA and urine being stored for future research into chronic diseases.

If you do agree to take part, you are free to withdraw at any time, without having to give a reason, and this will in no way affect your future health care.

What are the risks of the study?

Apart from the mild and temporary discomfort associated with a blood test there are no risks in being part of this study. Blood will only be taken by trained medical staff.

What happens to the urine sample?

10mL will be used to measure the amount of uric acid present in your urine. Uric acid levels below or above normal have been associated with a number of diseases including gout, cardiovascular disease, metabolic syndrome, diabetes, and multiple sclerosis. The remaining half of the sample will be stored for the future study of other compounds in urine that may be indicators of chronic disease.

What happens to the blood sample?

DNA will be isolated from the blood sample and used in future studies investigating genes associated chronic diseases. DNA will be stored indefinitely. It is possible that the investigators may need to collaborate with overseas researchers to carry out some specific gene studies. This would involve sending a small amount of your DNA overseas. In this situation, your DNA would still be under the custodianship of the investigators and any DNA not used up in the study will be returned to New Zealand.

How will the DNA be used?

Each person has a DNA make-up (their genes) which is different from that of everybody else - except in the case of identical twins. This genetic make-up is a mixture of the genes of our mother and father. The precise way they are mixed varies from child to child within the same family, so having the same parents does not mean that two children will have exactly the same genes. We already know that some health conditions and disorders are definitely inherited through the genes (hereditary conditions). Genes may also explain why some people are more resistant and some people are more prone to disorders which have not yet been identified as hereditary. The research which you are invited to participate in will investigate genetic make-up to look for any link.

Because the research will investigate genetic make-up, this is a way of identifying any individual participant and any particular characteristics of them genetically. This information will be confidential and will not be disclosed or used in any way without your informed consent. In particular, the researcher/sponsor of the research will not claim any right, ownership or property in your individual genetic information or that of your kinship group, hapu or iwi, without your having first sought and obtained informed consent to the transfer of any such right, ownership or property. Your consenting to participate in DNA sampling for the proposed study will not be construed as creating any right or claim on the part of the researcher/sponsor to your genetic information.

How will the information and samples collected in this study help identify risk factors for chronic disease?

The samples and information we collect will be used to help us to identify genetic factors (i.e. variations in DNA), biochemical factors (e.g. high uric acid) and lifestyle factors (e.g. smoking habits, alcohol consumption, type of job) that alter the risk of developing a chronic disease. For example, by determining how often a specific genetic variant occurs in a group of healthy people and comparing how often the same variant appears in a group of patients (e.g. with Crohn's disease) will help us to pin-

point which variations in DNA alter risk of developing a specific disease (e.g. Crohn's disease) and which variants are harmless and do not contribute to that disease. In a similar way, we can also compare various lifestyle factors between healthy people and patients. For example, if the number of smokers is markedly higher in a patient group than healthy people this suggests that smoking may increase risk of developing the disease being studied.

Expenses

A \$20 petrol voucher will be given to compensate for travel costs associated with providing blood and urine samples. This voucher will be sent to you after receipt of your blood and urine samples. There will be no payment for taking part in the study.

Confidentiality and Results

The data and samples collected from participants will only be used for the study of common chronic diseases found in New Zealand. No material that could personally identify you will be used in any reports on this study. Results of all testing will be coded by a system known only to the researchers. If you decide to withdraw from the study this will in no way affect any future medical care. The DNA and urine samples would then be destroyed before the sample analysis is performed, or if the testing has already been performed then the information would be destroyed. The collection of a set of controls is for future genetic studies into chronic diseases. Approval will be sought from the local Ethics Committee for each study.

Your Rights

If you have any queries or concerns regarding your rights as a participant in this study you may wish to contact a Health and Disability Advocate, telephone

- South Island (except Christchurch) 0800 377 766
- Christchurch 03 377 7501

Compensation

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the 2001 Injury Prevention Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators. If you have any questions about ACC, contact your nearest ACC office or the investigator.

If you have any questions concerning this study
please contact **Canterbury Chronic Diseases Study**

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<http://www.uoc.otago.ac.nz/research/chronic/index.htm>