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Genetics of NZ Families with Premature Coronary Heart Disease
(Upper South A Ethics Committee Approval No URA/11/09/049)

Information Sheet

You are invited to take part in a study of families/whanau with a strong history of early heart disease. You have been selected because you answered an advertisement about the study, or have contacted the study team to say you are interested in the research.

What is premature coronary heart disease?

- Coronary heart disease is the leading single cause of death in New Zealand, accounting for approximately 23% of all deaths per year. The commonest forms of coronary disease include angina and heart attack (myocardial infarction).
- If you develop coronary heart disease before the age of 50 years in men and 60 years in women, this is defined as premature (early) heart disease.
- First-degree relatives (parents, brothers, sisters or children) of patients who develop premature coronary heart disease have twice the heart disease risk compared to others in the population because of shared lifestyle risk factors and genetic predisposition.
- To understand why some families/whanau inherit a greater risk of premature heart disease, this study aims to identify gene variants associated with a strong family history of premature heart disease in local Māori and New Zealand European families.
- The ultimate goal is to improve risk prediction in New Zealand families with a strong family history of heart disease.

How can I help?

We are researching the genes that may be associated with coronary heart disease, by studying the pattern of genetic variation shared by first-degree relatives in families who have all suffered early heart disease compared with the genetics of individuals without heart disease. We invite you to donate a blood sample so that we can extract DNA, which comprises the body's genetic code. You will also be asked to answer a short questionnaire detailing your relevant personal medical history and your family history of heart disease and related conditions.

Will the results of my genetic analysis remain confidential?

Your information and blood sample will be given a code number, so that laboratory personnel will not know your identity. The details of your medical history relevant to the study may be reviewed by one of the study investigators, but they will treat this information confidentially. Your DNA sample will be stored in secure laboratory facilities identified by your sample's unique code number. You may withdraw your sample from the study without explanation at any time and your sample and data will be destroyed.

If you choose to participate in this genetic study, there may be repercussions from and for your whanau/family because you have given away genetic information. Whilst the sample given is from you, it will contain information shared by other whanau/family members and they may consider you do not have any right to give that information to others. You may wish to discuss the study with your family/whanau before you agree to disclose this information.

Will I or anyone else be given the results of my own genetic analysis?

At this stage the genetic analysis involved in this study will not allow prediction as to which individuals with certain gene combinations will get heart disease. Even when the genes involved in heart disease have been identified more precisely, it is still unlikely that precise individual predictions will be possible because there are many factors in our environment (eg our diet, or tobacco smoking) that interact with our genetic make-up to cause these diseases. Therefore, it would be unethical to provide individual genetic data to participants before their value in diagnosis, prediction, or treatment has been established. However, the composite findings of the study will be shared through newsletters to participants.

Any individual genetic information will remain confidential and will not be released to anyone else, for example your employer or your insurance company. No material that could personally identify you will be used in any reports on this study.

What do I have to do?

To help us in this work, we would ask you to:

- Come to the Nicholls Research Centre, Christchurch Hospital, after an overnight fast (nothing to eat or drink except water after midnight).
- Sign a form that gives your consent to take part in the study.
- Complete a questionnaire, which goes into your heart health and family history of heart disease. The questionnaire will take approximately 15 minutes to complete and you do not have to answer any question you don't want to.
- Give a blood sample (about 70 ml) from which we can extract some DNA, measure your cholesterol levels and measure other known markers of heart disease risk.
- Have your blood pressure, weight, height and waist measured.
- We estimate travel to and from Christchurch Hospital, finding a park and attending the clinic will take about 60 minutes, depending on the distance you have to travel to the hospital. We can provide a \$10 petrol voucher if you come by car or can arrange a taxi to pick you up if needed.

What health records will be accessed?

With your consent, your GP will be informed about your participation in this study. If during the course of the study it is suspected you may have a previously undiagnosed health problem both you and your GP will be advised. The study investigators may also obtain certain information specifically related to your heart health from your GP, to allow us to check on previous diagnoses made by your doctor and to check on prescribed medications. Information may also be obtained from your medical records and through the New Zealand Health Information Service, a division of the Ministry of Health, for admissions or hospital attendances outside Christchurch, at the start of the study and at 5 and 10 years, to check if you have had any further heart disease since joining the study.

Are there any risks?

Taking part in this study should not cause you any harm. Taking the blood sample may cause minor discomfort and occasional bruising.

Transfer of rights

If, in the future the results of this study allow for improved or new therapies and diagnostics then the University of Otago may involve a commercial company who would have a financial interest in such advances. Patent applications by the University of Otago relating to the results of this study may be required to maximise benefit for New Zealand. To allow the maximum benefit to be obtained from this research you are asked to waive any future claim to financial benefit through participation in this study. In this respect it should be noted that it is the whole collection of many DNA samples that is of value and each individual sample has no commercial value on its own.

Your involvement may help the current generation of people with cardiovascular disease and may offer radically new treatments for our children's generation.

Will my DNA or blood sample be used for anything else?

Your sample is being collected for research into heart disease. If you wish your blood sample and information to be used only for heart research please indicate this in the relevant question on the Consent Form when you donate your sample. Other researchers may apply to an accredited ethics committee to use the study's samples and medical history data for research into other genetic diseases in the future. If you are willing for your sample to be used in other studies choose this option on the Consent Form. Further studies on your sample will only be carried out with accredited ethics committee approval.

Who's going to do the research, and where will it be done?

This research will be done by Professor Vicky Cameron at the Christchurch Heart Institute, a University of Otago Centre of Research Excellence and the study team named at the top of this Information Sheet.

Some samples will be sent for immediate testing. Other samples will be frozen for later analysis. The sample you give (including DNA and plasma extracted from your blood) will be securely stored for the duration of the study, which could be as long as 20 years. Medical testing of samples is always advancing and we may be able to learn more about premature coronary heart disease by further testing at a later date.

Any samples that are still in storage at the end of the study will be disposed of. You have the option of choosing a standard disposal method or disposal with karakia (blessing).

Some sample analysis may be performed overseas by collaborating investigators developing similar tests for markers of heart disease. Any blood samples sent to sites outside New Zealand will be labelled with a coded number only. Unused samples will be destroyed by standard disposal (disposal by karakia will not be available in this instance).

Who is funding this study?

The Heart Foundation of New Zealand.

When is this research likely to benefit patients?

Identifying the genes that are relevant to heart disease is likely to take at least five to ten years. The new knowledge gained in this study may influence the way cardiologists (heart specialists) treat patients with heart disease and may help the development of new drugs by pharmaceutical companies.

Can I choose not to take part?

Yes, of course. Your participation in this study is entirely voluntary (your choice). If you choose not to participate, you don't have to give a reason why and it will not affect any future medical care you may receive. If you do agree to take part you are free to withdraw from the study at any time without having to give a reason. All remaining samples will be destroyed.

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 2001. ACC cover is not automatic, and your case will need to be assessed by ACC according to the provisions of the Injury Prevention, Rehabilitation, and Compensation Act 2001. 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.

You are also advised to check whether participation in this study would affect any indemnity cover you have or are considering, such as medical insurance, life insurance and superannuation.

Who should I talk to if I have any questions or concerns?

If you have any questions regarding this study, please telephone Judith Thomson, Study Coordinator on 03 364-1647 at the Christchurch Heart Institute, University of Otago, Christchurch. We also encourage you to talk to others, including your Iwi, about your involvement in the study.

If you have any queries or concerns regarding your rights as a participant in this study, you can contact an independent health and disability advocate. This is a free service provided under the Health and Disability Commissioner Act.

Telephone: (NZ wide) 0800 555 050

Free Fax (NZ wide): 0800 2787 7678 (0800 2 SUPPORT)

Email (NZ wide): advocacy@hdc.org.nz

On behalf of the researchers involved, we would like to thank you for considering participating in this study

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CONSENT FORM

1. Reference Number: _____ 2. Full Name: _____

2. Gender: _____ 3. Date of Birth: _____

Declaration:

I have read and I understand the information sheet dated 26 July 2013 for volunteers taking part in the study, which is designed to study the genetic basis of families/whanau with premature heart disease. I have had the opportunity to discuss this study and I am satisfied with the answers I have been given.

I understand that:

- I will be asked to complete a questionnaire about my medical history and family history of heart disease
- I will be asked to provide a blood sample
- The study may involve a review of my medical records specifically related to heart health

PLEASE ANSWER THE FOLLOWING QUESTIONS:

I have had the opportunity to use whānau support or a friend to help me ask questions and understand the study	YES / NO
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my future health care	YES / NO
I understand that my participation in this study is confidential and that no material which could identify me will be used in any reports on this study	YES / NO
I have had time to consider whether to take part	YES / NO
I know whom to contact if I have any questions about the study	YES / NO
I am aware that the proposed study will involve analysis of my genetic makeup. I consent to such an analysis being performed	YES / NO
I give my consent for the use of my blood, and materials prepared from it, for genetic studies in heart diseases and understand that, for these purposes, my DNA and plasma samples may be stored for up to 20 years	YES / NO
I understand that a sample may be sent overseas for analysis as part of this study into heart disease	YES / NO
I understand that if in the future the results of this study allow for improved or new therapies and diagnostics then the University of Otago may involve a commercial company who would have a financial interest in such advances.	YES / NO
I transfer to the University of Otago any property rights I might have in the blood I provide and materials prepared from it. I consent to the making of patent applications relating to the results of those studies, without any payment to me or my heirs and without any acknowledgment of my contribution.	YES / NO

I understand additional research on my blood/DNA samples will not be undertaken unless further approval is sought and granted by an approved ethics committee.	YES / NO
I agree that I may be contacted in future and invited to participate in other approved health research studies	YES / NO
I consent to my blood sample being used in other ethics committee-approved studies	YES / NO
I agree to my GP or other current health provider being notified of my participation in the study and to be advised about any previously undiagnosed problems revealed by this study	YES / NO
My GP is: _____ GP's Practice: _____	
I request any remaining blood sample be destroyed at the end of the study (circle one): By Standard Disposal, or With appropriate Karakia	

I _____ (please write your full name) hereby consent to take part in this study.

Signature of Participant : _____ **Date:** _____

FULL NAMES OF RESEARCHERS

Professor Vicky Cameron
Ms Judith Thomson
Dr Anna Pilbrow
Mrs Suzanne Pitama
Miss Allamanda Faatoese
Associate Professor Richard Troughton
Associate Professor Chris Frampton

Contact Number for Researchers: 03 364-1647

Project explained by: _____

Project Role : _____

Signature of Witness : _____

Date: _____