Study title: Anorexia Nervosa Genetics Initiative (Aotearoa New Zealand)

Locality: University of Otago, Christchurch

Lead investigator: Professor Martin Kennedy

Co-investigator: Dr Jennifer Jordan

Contact phone number: 03-3641222

Contact phone number: 03-3720400

Following your completion of the online eating disorder survey, you are invited to take part in the second part of the ANGI project, a study on understanding the genetics of anorexia nervosa. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in the second part of this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 8 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

• Anorexia nervosa is a medically serious condition with significant psychological and social effects on individuals and impacts on their families.

• We know that genes are involved but still have much to learn about the biology of anorexia nervosa, and there is still conflicting evidence about causes, diagnostic issues, and how best to treat those with eating disorders.

• The Anorexia Nervosa Genetics Initiative (ANGI) project is an international research collaboration bringing together researchers, clinicians and geneticists with established track records in eating disorders and genetics from the United States, the United Kingdom, Sweden, Denmark, Australia, and now New Zealand.

• The ANGI project aims to collect the largest sample of those with a lifetime history of anorexia nervosa to identify genes contributing to risk factors and pathways into anorexia nervosa and informing new treatment approaches. This research may eventually lead to better prevention and treatment of anorexia nervosa.

• Large samples and international collaborations of researchers working together maximize the chances of answering important fundamental research questions such as how genes operate in anorexia nervosa.
• We will recruit New Zealand participants with a history of anorexia nervosa during 2014-2016, collecting clinical information and blood samples from at least 300 individuals.
• The study has received ethical approval from the Southern Health and Disability Ethics Committee (No. 14/STH/115).

New Zealand investigators
Professor Martin Kennedy, molecular genetics researcher, Department of Pathology, University of Otago, Christchurch.
Dr Jennifer Jordan, clinical psychologist/senior research fellow, Department of Psychological Medicine, University of Otago, Christchurch.
Other Christchurch staff involved in this study: Bridget Kimber, Wendy Mayes.

International investigators
Professor Cynthia Bulik, Distinguished Professor of Eating Disorders, Co-Director, UNC Center for Psychiatric Genomics, University of North Carolina at Chapel Hill, USA.
Professor Nick Martin, Queensland Institute of Medical Research, Queensland.
Professor Tracey Wade, Flinders University, South Australia.
Professor Preben Bo Mortensen, Aarhus Universitet, Aarhus, Denmark.
Professor Mikael Landén, Karolinska Institutet, Stockholm, Sweden.

How is the study funded? Research grants have been obtained within New Zealand for the costs of recruiting and collecting, storing and transporting blood samples for the New Zealand arm of ANGI. The costs of analysing the genes will be met by research grants obtained within the United States of America. The Klarman Family Foundation, a philanthropic organization with an interest in funding health research is a major funder of the consortium through grants to Professor Cynthia Bulik.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Who will take part in this study?
Males and females aged 14 years and older with a history of anorexia nervosa over their lifetime. You may have seen an advertisement or may have heard about this study from a health service or support group. Your participation is optional, i.e. it is your decision. If you are under 18, your parents or guardian will also need to sign the consent form for you to participate.

The questions in this international questionnaire are in English, so we are not able to provide interpreted versions of these forms. If you have any difficulties in understanding or completing these forms, please contact us for assistance.

What will my participation involve?
Information has been collected directly from you by your completion of the online survey that asked questions about you, your lifestyle, eating habits, patterns and behaviours. Analyses of your blood sample will provide genetic data. No other information will be collected. The information about specific symptoms and types of eating disorder behaviours from the survey will be linked to findings from the genetic analyses.

If your survey results indicate that you met full criteria for anorexia nervosa, you will be contacted by our researchers and if you consent to participate, you will be sent a blood sample pack and instructions to take this to a local clinic where your blood sample will be taken by an appropriately qualified health professional. If you are in Christchurch, you may be asked to attend the Department of Psychological Medicine (at the Medical School) for the blood test. A 30mL sample of blood (less than three tablespoons full) will be drawn and this will be used for...
research purposes. The DNA in your blood sample will be used to help discover genes that may influence eating disorders, using the latest technologies available for genetic research and gene discovery.

Your survey data and blood sample will be given a unique identifying code to ensure your confidentiality. A portion of your blood sample (20mL) will be sent initially to our Australian collaborators at the QIMR Berghofer Medical Research Institute (QIMR Berghofer) where it will be stored in transit and then shipped in larger batches to the Rutgers University Repository of National Institutes of Health in the USA. This is a scientific resource that holds information from many individuals, including medical and genetic information. Here, DNA will be taken from the blood sample and used for scientific research now and in the future. DNA and information about your sample will be stored in this repository. One tube of your blood will be retained in a freezer at the University of Otago, Christchurch, within the facilities of the Cancer Society Tissue Bank.

Once generated, your coded genetic information will be held in the National Institutes of Health data repository, called database of Genotypes and Phenotypes (dbGaP), at the National Center for Biotechnology Information (NCBI) in the USA. dbGaP is a controlled-access database, which means that the information in this database will be available only to researchers from around the world who are approved to study how genes contribute to a variety of health conditions. These scientists will not know your name or other personal information.

The blood and DNA you provide (but NOT your name or address) may be made available to other researchers studying health and behaviour in the future, some of whom may have commercial interests. If you consent to participate, you will be donating your blood freely for these purposes and waive any claim to commercial rights arising from this work.

In addition to being used for research in this current project, your blood sample will be stored indefinitely and may be considered for use in future projects (provided you consent to this future research). Before any such work is able to proceed it will be subject to review by the appropriate research ethics committees.

Confidentiality:
The data and samples collected from participants will only be used for the purposes above. 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.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Possible benefits:

There are no specific benefits to you in participating. Your participation may benefit future generations by helping medical researchers understand how genes contribute to eating disorders. Donating your sample may also help with the discovery of new diagnostic tests and better treatments to manage the symptoms associated with eating disorders.

Possible risks:

Apart from the mild and temporary discomfort associated with a blood test there are no risks from contributing the blood samples. Blood will be taken by trained medical staff at appropriate facilities.

Because we may carry out quite extensive analysis of your genes, it is possible we could discover something not related to the research question, which is of major relevance to your health or your family’s health. If this situation (called “incidental findings”) arises, we will seek advice from a medical geneticist about this finding, and if they consider it important to your health, we will arrange for them to contact you to discuss this with you. You have a choice whether or not to be informed of these findings if they occur. If we do inadvertently discover something of major health significance that is reported back to you, it is important to note that this information could be considered “prior knowledge” of a medical condition.
This knowledge may potentially impact on your right to receive cover for the medical condition through any private medical insurance scheme to which you belong.

There may be cultural issues associated with storing and sending your samples overseas and these should be discussed with your family/whānau as appropriate. Whilst the sample given is from you, it will contain information shared by other whānau/family members and they may consider you do not have the right to give that information to others. We suggest that your family/whānau is involved with you at all stages of the research. Some whānau disagree with storage of blood samples citing whakapapa, and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose whether they participate or not. Te Runanga o Ngai Tahu, who are mana whenua of this area, do not support genetic research. The same sentiments may be shared with other Iwi.

### WHO PAYS FOR THE STUDY?

This study will be paid for by research grant money applied for by the investigators. There is no direct cost to you in participating. There will be no payment for taking part in the initial survey. If you are invited to participate in the genetic research component of the study, once you provide blood samples you will receive a $25 voucher as a token recognition of the time and inconvenience in participating.

### WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

### WHAT ARE MY RIGHTS?

Participants have the right to access survey information collected from them as part of the study. However it will not be possible to provide meaningful interpretations of genetic information on an individual basis.

### WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

If you do agree to take part in this study, 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. If you withdraw consent at any time in the future, your DNA and blood will be destroyed or if the testing has already been performed, then the information would be destroyed. You have the option of choosing a standard disposal method for your remaining samples, or disposal with karakia (blessing).

If you withdraw consent for the study, any information about you will not be used in the future but some information may have already been published as part of the study. We are unable to retract this information at this point.

### Results

We aim to have the results published in the international medical literature. Individual participants will not be identified in any such publications. It will take some time for the results to be completed after you have taken part in the study, and we will inform you by email or letter of any findings, and publications will be listed on the website of the University of Otago, Christchurch.
WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

Please feel free to contact the researchers if you have any questions about this study. If you have concerns or complaints about the study at any stage, you can contact the researchers, and or/ the other agencies below.

Dr Jennifer Jordan  
Senior Research Fellow/ Clinical Psychologist  
Tel 03-3720400  
Email: jenny.jordan@otago.ac.nz

Professor Martin Kennedy  
Tel: 03-364 1222  
Email: martin.kennedy@otago.ac.nz

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:  
Phone: 0800 555 050  
Fax: 0800 2 SUPPORT (0800 2787 7678)  
Email: advocacy@hdc.org.nz

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study on:  
Phone: 0800 4 ETHICS  
Email: hdecs@moh.govt.nz
CONSENT FORM

Please tick to indicate you consent to the following

I have read, or have had read to me and I understand the Participan Information Sheet.  
Yes ☐  No ☐

I have been given sufficient time to consider whether or not to participate in this study.  
Yes ☐  No ☐

I have had the opportunity to use a legal representative, whanau/family support or a friend to help me ask questions and understand the study.  
Yes ☐  No ☐

I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.  
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 without this affecting my medical care.  
Yes ☐  No ☐

I consent to the research staff collecting and processing survey information from me, including information about my health.  
Yes ☐  No ☐

If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.  
Yes ☐  No ☐

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.  
Yes ☐  No ☐

I understand the compensation provisions in case of injury during the study.  
Yes ☐  No ☐

I know who to contact if I have any questions about the study  
Yes ☐  No ☐

I consent to being contacted in the future to ask about participating in related studies  
Yes ☐  No ☐

I wish to receive a summary of the results from the study.  
Yes ☐  No ☐
Specific consents for blood samples and related future research

I agree to my blood or DNA samples being sent overseas  
Yes ☐ No ☐

I am aware that the study will store my DNA (genetic make-up) for this research project and that the samples will be stored indefinitely, with one sample at the University of Otago, Christchurch (Cancer Society Tissue Bank facility) and a portion of my blood sample (20mL) will be stored in transit at the QIMR Berghofer Medical Research Institute before being sent to and stored at the Rutgers University Repository of National Health Institute (NIH) in the United States of America.  
Yes ☐ No ☐

I am aware that this study will involve potentially extensive analysis of my genetic makeup.  
Yes ☐ No ☐

I am aware that the genetic analysis may produce unexpected results of potential health or reproductive significance that are unrelated to this research on anorexia nervosa. I wish to be notified of any additional findings of health significance should they arise.  
Yes ☐ No ☐

If I decline to be notified about additional findings of health significance, I can contact the researchers if I change my mind  
Yes ☐ No ☐

I agree for my blood samples to be stored and used in future research but only on subjects related to the current research project: [Anorexia Nervosa Genetics Initiative]  
Yes ☐ No ☐

I give permission for my blood samples to be stored indefinitely  
Yes ☐ No ☐

If I choose to withdraw from the study, I request that samples of my blood and/or DNA are:  
Yes ☐ No ☐

- disposed of using established guidelines for discarding biohazard waste  OR…

- returned to New Zealand for disposal with karakia (blessing)

Optional consent for future unspecified research

I agree for my survey data to be stored and used in future research of any type which has been ethically approved  
Yes ☐ No ☐

I agree for my blood samples to be stored and used in future research of any type which has been ethically approved  
Yes ☐ No ☐

Continued over
Declaration by participant:

I hereby consent to take part in this study.

Participant’s name:

Signature: ___________________________ Date: ___________________________

Declaration by parent or guardian for participants under the age of 18:
I hereby consent to my son/daughter participating in this study.

Parent or guardian’s name:

Signature: ___________________________ Date: ___________________________

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher’s name:

Signature: ___________________________ Date: ___________________________