QIMR Berghofer
Medical Research Institute

EDGI2
EATING DISORDERS GENETICS INITIATIVE

Participant Information Sheet - Adult

1 Introduction

Title	Eating Disorders Genetics Initiative 2
Short Title	EDGI2
Protocol Number	P3550
Project Sponsor	QIMR Berghofer Medical Research Institute
Coordinating Principal Investigator	Professor Nick Martin, QIMR Berghofer, QLD
Associate Investigators	Professor Cynthia Bulik, University of North Carolina, USA
Location	Australia

You are invited to participate in this research project, which is called the ‘Eating Disorders Genetics Initiative 2’, or EDGI 2.

We are seeking people 18 years of age and over who have experienced an eating disorder (ED) at any time in their life to participate. We are also seeking people who have never had an eating disorder (controls).

This Participant Information Sheet/Consent Form tells you about the research project. It explains what is involved in the study to help you decide if you want to take part.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your doctor.

If you decide you want to take part in the research project, you will be asked to provide your consent online. You will be able to save an electronic copy of this Participant Information Sheet and Consent Form to keep.

2 What is genetic epidemiological research?

Genes are made of DNA – the chemical structure carrying your genetic information that determines many human characteristics such as the colour of your eyes or hair. Researchers study genes in order to understand why some people have a certain condition, such as Anorexia Nervosa, and why some people do not. Understanding a person’s genes may also explain why some people respond to a treatment while others don’t, or why some people experience side effects and others do not.

3 What is the purpose of this research?

Anorexia Nervosa (AN) is a severe mental illness causing significant disability and burden, afflicting 3% of females and .03% of males. Bulimia Nervosa (BN) and Binge Eating Disorder (BED) are more common than AN and carry substantial morbidity and profoundly impact quality of life. Avoidant Restrictive Food Intake Disorder (ARFID), characterised by extreme picky eating, can cause serious, and sometimes life-threatening, medical consequences. Researchers so far have only scratched the surface in understanding the causes of eating disorders. EDGI researchers propose to use genetics to understand the biology of Eating Disorders and, in turn, the pathways and systems that influence these complex diseases.

We are seeking 4,000 participants who have experienced an eating disorder at some time in their life to help us reach this goal. We are also seeking people who have never had an eating disorder (controls). In research, case/control studies compare groups of people with different experiences (e.g., with and without AN) but who are otherwise similar, for instance, in terms of their age, background, and geographical location. This enables researchers to be certain any results they find are from the effect being measured, and not something else.

This research has been funded by a grant from the National Institute of Health (NIH), USA.

4 What does participation in this research involve?

There are 3 parts to this study:

(i) In the first part of this study, you will be asked to complete an online consent form. We will then ask you for your contact details so we can contact you about the study;

(ii) After giving your consent, you will be asked to complete an online questionnaire. This questionnaire has two stages: a core module about experiences with eating disorders (15-20 minutes) and a supplement stage about other health information related to eating disorders (approximately 30 to 40 minutes).

(iii) Depending on your responses to the core online questionnaire, you may be asked to donate a saliva sample. We will extract your DNA from your sample to investigate genetic risk factors for eating disorders. To collect your sample, we will send you a specialised collection container for your sample. The collection kit is easy to use and the sample can be collected in your own home at your convenience. You will be asked to return this sample via Australia Post to our laboratory, at no cost to you.

Altogether completing the online questionnaire will take approximately 50 minutes, but may take less time. For your convenience, the survey is designed so that you can start a module and return to it later where you left off.

There are no additional costs associated with participating in this research project, nor will you be paid.

5 Do I have to take part in this research project?

Participation in this research project is voluntary. If you do not wish to take part, you do not have to. If you do not wish to take part you do not have to do anything. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

6 What are the possible benefits of taking part?

This study is unlikely to be of any immediate and specific benefit to you. Extensive research is required to find answers to the questions we are studying. However, future medical or scientific discoveries may come from the research in which you participate. These may help improve the available treatments and outcomes for people suffering Eating Disorders.

7 What are the possible risks and disadvantages of taking part?

You may feel that some of the questions we ask in the questionnaire are uncomfortable, stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If your responses to questions in the online questionnaire indicate that you are at significant risk of serious harm, you will be provided with advice on how to seek appropriate counselling, support or formal health care.

8 What will happen to information about me?

All personal and questionnaire data collected, and information linked for the study remains confidential in accordance with the National Health and Medical Research Council (NHMRC) ethical guidelines and the Privacy Act. Your personal details, questionnaire data and genetic data will all be stored separately. The only link between your personal details and your other data is your participant identification number. Linking your personal details and other data using this number is restricted to members of the QIMR Berghofer research team. All information about you will be stored securely, with access restricted to members of the research team.

The researchers will store your other personal, questionnaire and genetic information indefinitely at QIMR Berghofer Medical Research Institute. This information may continue to be valuable to researchers many years into the future, and may be considered for use in future, related projects. Before any future work proceeds it will be subject to approval by the relevant ethics committees.

Your genetic information and some of your questionnaire information (not your name or other personal details) may eventually be put into an international genetics data repository. Information in the database will be available only to researchers from around the world who are approved to study how genes cause a variety of health conditions. These scientists will not know your name or other personal information we learn about you.

Results of this research project may be presented in scientific papers in medical literature, or in public talks, but your identity will not be revealed. The data collected as part of this study will be combined at analysis with the data from many other people, and as such there will be no way of identifying you as a participant.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

By confirming your consent online you consent to the research team collecting and using personal, questionnaire and genetic information about you as described for the research project.

9 What will happen to my biological sample?

We will use your biological sample to extract one or more samples of DNA. The research team will then look for differences and similarities between participants' DNA samples. This information can help us understand why some people have a certain eating disorder and some people do not.

Your biological sample and extracted DNA samples will be stored securely at QIMR Berghofer Medical Research Institute along with samples from many other people. They will be re-identifiable, which means that they will be stored with a barcode label, and can be identified as yours even though your personal details are stored separately. Linking your personal details with your biological sample or DNA using the barcode is restricted to members of the QIMR Berghofer research team.

We may send part of your DNA to another laboratory (which may be overseas) for genetic processing and analysis. This is called genotyping. If this occurs, your part sample will only be labelled with a number, and transported along with samples from many other people. No information about you will be sent to or accessible by the other laboratory. Any sample remaining after genetic processing or analysis by another laboratory will be destroyed.

We will store the remainder of your DNA sample indefinitely. We may send a small portion of your DNA to a scientific research repository established by the National Institutes of Mental Health (NIMH) in the USA for indefinite storage. If this occurs, your part sample will only be labelled with a unique number, a number not used in any other phase of the study, and transported along with samples from many other people. No information about you will be sent or accessible by this repository. Your sample will be used for future research on psychiatric disorders, related medical conditions and/or other health conditions. Access to the repository is strictly limited and all applications will be reviewed by the NIMH review panel. QIMR Berghofer will store any remaining DNA samples for use in future research studies that may or may not be related to the original research project. The purpose of storing these types of samples is to answer questions in the future, so we expect to keep your samples for a long time.

10 Will I be given the results of the research project?

This research is not designed to provide any clinical or genetic results to participants, and is not intended for the purpose of treating any health problems you may have. Participation in this research study does not take the place of visits to a doctor or other health professionals.

Your information will be used for research purposes and you will not be given any clinical results from this study. Your information will be analysed in combination with information from other participants in this study. The nature of the research means that the data is de-identified prior to analysis, and only results of a global (not individual) nature will be produced. It will therefore not be possible to provide any individual results from the study.

11 Who has reviewed the 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 HREC of the QIMR Berghofer Medical Research Institute (QIMRB-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.

12 What if I don't want to participate or what if I change my mind later and want to withdraw from the study?

Participation is voluntary and you can choose not to participate. If you do choose to participate you can withdraw from the study at any time, at any stage, or for any reason for some, part, or all of the research. You can withdraw your consent to participate in this research project by completing a “Withdrawal of Consent” form. This form can also specify whether you wish to have your saliva sample, which has already collected and stored, deleted, destroyed or returned to me if it is still identifiable as mine.

Once the researchers have been notified, your remaining sample will be destroyed. If you do not make such a request, the sample may be stored forever. Note that any analysis in progress at the time of your withdrawal or already performed prior to your request being received by the researcher will continue to be used as part of the research study.

You can withdraw your consent by contacting the Project Coordinator by phone 1800 257 179 (freecall) or email edgi@qimrberghofer.edu.au. These contact details will be listed on your correspondence with the project team.

13 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project, you can contact the project coordinator:

Name	Richard Parker
Position	Project Coordinator
Telephone	07 3362 0297 or Freecall 1800 257 179
Email	richard.parker@qimrberghofer.edu.au

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 name	QIMR Berghofer Medical Research Institute Ethics Committee
HREC Executive Officer	Secretary to the Chairperson of the Ethics Committee
Telephone	07 3362 0117
Email	HREC.Secretariat@qimrberghofer.edu.au

If you **do** want to participant, please click the 'Continue' button below.

If you **do not** want to participate, thank you for your time. You are not required to respond in any way. You may close the browser window to exit.

Consent Form

If you'd like to participate in this study, we need you to tell us below that you've understood what is involved in participating and that you are giving us permission to collect and store the information, biological (saliva) sample and DNA that you provided us.

Clicking on the "agree to participate" button below indicates that:

Declaration by Participant

- I have had an opportunity to ask questions and acknowledge that the nature, purpose and contemplated effects of this research study have been fully described to my satisfaction.
- I understand that I am free to withdraw from this study at any time during the project without affecting my future health care.
- I voluntarily give my consent to participate in the research study 'EATING DISORDERS GENETICS INITIATIVE' as described in the Information Sheet, to help discover genes that may influence the risk for, and treatment of, eating disorders, as well as related health and behaviour conditions, using the latest technologies available for genotyping, sequencing and gene-expression analysis.
- I acknowledge that my survey information, saliva sample and DNA from this study will be stored indefinitely and may be considered for use in the future related projects, including uses not directly related to this study, subject to review by the appropriate research ethics committees.
- I acknowledge that some of my genetic information (but not my name or any personal details) may eventually be put into an international genetics data repository for indefinite storage for future research on psychiatric disorders, related medical conditions and/or other health conditions, subject to review by the appropriate research ethics committees.
- I acknowledge that a small portion of my saliva sample (but not my name or any personal details) may be stored in the National Institutes of Mental Health (NIMH) in the USA for indefinite storage for future research on psychiatric disorders, related medical conditions and/or other health conditions, subject to review by the appropriate research ethics committees and strict NIMH access controls.
- I agree to be contacted about future, related studies and understand that I am in no way obligated to participate, and can freely withdraw from this request without affecting my rights or the responsibilities of the researchers in any respect.
- I understand all information gathered during this research project will be treated in a strictly confidential manner in accordance with the National Health and Medical Research Council (NHMRC) Guidelines and the Commonwealth Privacy Act.
- I understand that I will be able to save an electronic copy of this document to keep.

If you do not want to participate, thank you for your time. You are not required to respond in any way. You may close the browser window to exit.

Do you consent to participate in the EDGI2 research study?

☐ Yes
☐ No

This research is being conducted under the supervision of Professor Nick Martin at the Genetic Epidemiology Unit, QIMR Berghofer Medical Research Institute, and has been approved by the QIMR Berghofer Human Research Ethics Committee (QIMRB-HREC approval P3550).