Participant Information Sheet

Title	The Genetics of Dizygotic Twinning
Short Title	GDZT
Protocol Number	P3693
Project Sponsor	QIMR Berghofer Medical Research Institute
Coordinating Principal Investigator	Professor Nick Martin, QIMR Berghofer
Associate Investigators	N/A
Location	Australia

1 Introduction

You are invited to participate in this research project called ‘The Genetics of Dizygotic Twinning’.

We are seeking women 18 years of age and over, who have given birth to one or more sets of non-identical (dizygotic, or DZ) twins.

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 the purpose of this 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 have discovered that there is a genetic component to having non-identical (DZ) twins (in other words, having non-identical twins runs in families). We want to study these genes further, in order to understand why some people have non-identical twins and others do not. We also want to find some more genes that may contribute to non-identical twinning. To find more genes, research studies need a large number of participants, so we would like to collect information from as many people in Australia as we can. Some of the genes we have already found that are related to DZ twinning also control female fertility. So finding the genes responsible for non-identical twinning may also reveal important information about female fertility and infertility.

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 a short online questionnaire about your twins and other related information. Completing the online questionnaire will take approximately 10 to 15 minutes, but may take less time.

(iii) Depending on your responses to the online questionnaire, you may be asked to donate a saliva sample. We will extract your DNA from your sample to investigate genetic factors for non-identical twinning. To collect your sample, we will send you a specialised collection container. 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 pre-paid Australia Post to our laboratory, at no cost to you.

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 our understanding of genetic factors, including female fertility, that are important for conceiving and carrying DZ twins.

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

You may find some items in the questionnaire stressful or upsetting. No survey items are compulsory, so if you do not wish to answer a question during the questionnaire, you may skip it and go to the next question, or you may stop immediately if you do not wish to continue.

If you find you are distressed by completing the questionnaire, there are mental health support services available to you to contact 24 hours a day, 7 days a week. We have included below the phone numbers for Lifeline and Beyond Blue should you feel you require support.

Lifeline: 13 11 14

Beyond Blue: 1300 224 636

8 What will happen to information about me?

All personal, genetic and questionnaire data collected 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, which will be randomly assigned after you have completed the questionnaire. 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.

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 higher incidence of having non-identical twins, and will add to what we know about female fertility and infertility.

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. QIMR Berghofer will store any remaining DNA samples for use in future related research studies. 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 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, incorporating all subsequent updates)". 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. However, any data that has already been used in aggregate analyses will be unable to be destroyed, and personal information already collected will need to be retained in order to measure the results of the study properly and to comply with law. Any data not already in use by researchers may be destroyed. You can withdraw your consent by contacting the Project Coordinator by phone 1800 257 179 (freecall) or email jessica.adsett@qimrberghofer.edu.au. Contact details will be listed on any 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	Jessica Adsett
Position	Project Coordinator
Telephone	07 3362 0225 or Freecall 1800 257 179
Email	jessica.adsett@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 not wish to participate, thank you for your time. You are not required to respond in any way. You may close the browser window to exit.

☐ I have read this information sheet and have understood it.

Save and Continue

QIMR Berghofer
Medical Research Institute

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 'The Genetics of DZ Twinning' as described in the Information Sheet, to help discover genes that may influence non-identical twinning, 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, subject to review by the appropriate research ethics committees.
- 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.

☐ Agree to participate **[Date and time automatically recorded]**

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 P3693).

Save and Continue