Participant Information Sheet

Introduction

Title	Genetics of Risk and Response to Treatment of Depression
Short Title	MDD
Protocol Number	P2118
Project Sponsor	QIMR Berghofer Medical Research Institute Queensland Brain Institute, University of Queensland Brain and Mind Centre, University of Sydney South Australian Health and Medical Research Institute
Coordinating Principal Investigator	Professor Nick Martin
Associate Investigators	Professor Naomi Wray Professor Ian Hickie Professor Julio Licinio Dr Enda Byrne Associate Professor Sarah Medland
Location	Australia

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1 Introduction

You are invited to participate in this research project, which is called 'Genetics of Risk and Response to Treatment of Depression'.

We are seeking people 18 years of age and over to participate in the study.

People who have experienced depression and those who have never had depression are eligible to participate.

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.

If you do not wish to take part in this study, you do not have to. The project investigators do not have your name or contact details unless you provide them, so if you do not wish to take part you do not have to do anything.

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 depression 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 don't.

3 What is the purpose of this research?

Major depressive disorder (MDD) is a common mental illness affecting one in five people at some time in their life. Family studies suggest there is an important genetic contribution to MDD. MDD is more prevalent than other mental health disorders and is influenced more by environmental risk factors. The purpose of the research project is to identify specific genetic risk factors associated with differences between individuals in both risk of depression and response to treatment. We hope that this research will help us learn more about MDD, and the factors influencing why various treatments for MDD are successful for some people and not others.

For this study we hope to recruit at least 10,000 people who have major depressive disorder (MDD), as well as at least 2,000 people with no history of MDD. This research has been funded by the National Health and Medical Research Council.

4 What does participation in this research involve?

There are 5 parts to this study:

(i) Before providing any of your personal information, you will be asked to complete an online consent form.

(ii) Then you will be asked to complete a short 15-20 minute core online questionnaire about depression and medication you may have been prescribed.

(iii) You will then be presented with a series of additional online modules asking you about:

- your family background;
- education;
- general health;
- medical history;
- experiences with mental health;
- medical treatment you may have received;
- substance use;
- sleep patterns; and
- a broad range of life experiences.

Completing the full set of modules will take approximately 60 minutes, but may take less time. For your convenience, the modules are designed so that you can start any one you wish and return to it later where you left off.

(iv) Depending on your responses to the core online questionnaire (ii), you may be asked to donate a saliva sample. We will extract your DNA from your sample to investigate genetic risk factors for depression and medication response. 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.

(v) Some details of your medical history that would be helpful to the project investigators (like how many prescriptions you may have had for various medications) would be hard for many people to remember. So we will ask for your permission to access your Medicare and Pharmaceutical Benefits Scheme (PBS) claims information from the last five (5) years. Medicare collects information on your medical visits and procedures, and the associated costs, while the PBS collects information on the prescription medications you have filled at pharmacies. If you agree, you will be asked to fill out a consent form authorising the study access to your Medicare and Pharmaceutical Benefits Scheme data as outlined on the consent form. The consent form will be sent securely to the Department of Human Services which holds your Medicare and PBS information confidentially. Consent to access your Medicare and/or PBS claims information is completely separate from consent for the rest of the study (online questionnaire and biological sample). You can participate in the other parts of this study without consenting to the Medicare and PBS component.

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. The project investigators do not have your name or contact details unless you provide them, so 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 depression.

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 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 specific advice on how to access appropriate counselling, support or formal health care. If appropriate, you may wish to be contacted by qualified professionals who are not members of the research team. This contact will be provided free of charge.

8 What will happen to information about me?

All personal, questionnaire and genetic information collected 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.

Any Medicare and Pharmaceutical Benefits Scheme (PBS) data you consent to provide (including the consent form itself) will be used for the purposes of this study only. It cannot be shared with anyone outside the research team for this project without specific Commonwealth Government approval. The original records supplied to the research team, and any copies, will be deleted from our computer systems 7 years after the publication of the final project report. However, any research findings associated with your Medicare or PBS data will not be able to be destroyed or recalled.

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 (but not your name, other personal details, Medicare or PBS data) 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 condition such as depression and some people do not, or why some people respond to a treatment while others don't.

Your biological sample and samples of your DNA 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 wish to send part of your biological sample and/or a sample of your DNA to another laboratory (which may be overseas) for processing or analysis. 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 processing or analysis by another laboratory will be returned to QIMR Berghofer Medical Research Institute for indefinite storage.

We would like to store your biological and/or DNA samples for use in any future research studies that may or may not be related to the original research project. There is no direct benefit to you from the storage of your biological and/or DNA samples. In the future, other doctors and scientists at this and other medical and research centres may use your samples to learn about many different diseases and conditions. Their goal is to improve health outcomes and develop new treatments. 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). This statement has been developed to protect the interests of people who agree to participate in human research studies.

12 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:

Research contact person:

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 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.

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

Save and Continue

Sample Collection

Are you willing to provide a saliva sample for this study?

- We will send you a specialised collection container for your sample
- You will be asked to return this sample via Australia Post to our laboratory, at no cost to you.

○ Yes
○ No

Save and Continue

QIMR Berghofer Medical Research Institute | The University of Queensland Australia | qbi queensland brain institute | The University of Sydney | SAHMRI

Consent Form – Participant Providing Saliva Sample

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be able to save an electronic copy of this document to keep.

I give permission for the storage and use of my personal, questionnaire and genetic information for the purpose of future research projects that may or may not be related to this research project.

I give permission for the storage and use of my saliva sample and DNA for the purpose of future research projects that may or may not be related to this research project

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 and continue to survey

Save and Continue