# Participant Information Sheet

## Introduction

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| **Title** | Living with Anxiety Study |
| **Short Title** | LWA |
| **Protocol Number** | P3910 |
| **Project Sponsor** | QIMR Berghofer Medical Research Institute<br>Brain and Mind Centre, University of Sydney |
| **Coordinating Principal Investigator** | Professor Sarah Medland |
| **Associate Investigators** | Professor Nick Martin<br>Professor Ian Hickie |
| **Location** | Australia |

### 1 Introduction

You are invited to participate in this research project, which is called the 'Living with Anxiety Study'. We are seeking people 18 years of age and over to participate in the study.

People who have experienced anxiety disorders at any time in their life 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 an Anxiety Disorder 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?

Anxiety Disorders are common mental illnesses causing significant disability and burden, affecting almost 1 in 3 Australians during their lifetime. Family studies suggest there is an important genetic contribution to Anxiety Disorders.

The purpose of the research project is to identify specific genetic risk factors associated with differences between individuals in both risk of Anxiety Disorders and response to treatment. We hope that this research will help us learn more about this disorder, and the factors influencing why various treatments for Anxiety Disorders are successful for some people and not others.

For this study we hope to recruit at least 5,000 people who have Anxiety Disorder. This research has been funded by the Medical Research Future Fund (MRFF), an initiative of the Australian Government to fund health and medical research.

***Your participation is voluntary***

Your participation in this study is completely voluntary and there will be no cost to you. If you do not want to take part in this study you do not have to. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not affect your current and future medical care in any way.

## 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 30 minute online questionnaire about Anxiety Disorders and medication you may have been prescribed.

(iii) There are some optional follow-up questionnaires which ask 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.

For your convenience, the questionnaires 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, you may be asked to donate a saliva sample. We will extract your DNA from your sample to investigate genetic risk factors for Anxiety Disorders 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 Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) claims information for a period of ten (10) 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 an online consent form authorising the study access to your Commonwealth health information provided by Services Australia, see the separate Services Australia Participant Information Document and Participant Consent Form. The consent form will be sent securely to *Services Australia* 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.

Services Australia is not involved in this research other than to provide the information that you have consented to the release of, should you decide to participate in this study. Services Australia has confirmed that this research and any associated documents have received approval from a Human Research Ethics Committee (HREC) that is registered with and operates within guidelines set out by the National Health and Medical Research Council (NHMRC).

There are no financial 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.

You are under no obligation to continue with the research study. People withdraw from studies for various reasons and you do not need to provide a reason. You can withdraw from the study at any time by contacting the research team and requesting a withdrawal of consent form for you to complete and sign.

If you withdraw from the study, your information that has already been analysed and/or included in a publication may not be able to be withdrawn or destroyed. In such circumstances, your personal information will continue to form part of the project/research study records and results. Your privacy will continue to be protected at all times.

## 6 Do I have to give a DNA sample?

For eligible participants, the LwA study will also involve providing a saliva sample, which can be done in the comfort of your own home. Even though not everyone will be asked to donate a saliva sample, all information provided in the survey is extremely valuable to our research. You can also choose to complete the surveys but not provide a saliva sample.

## 7 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 living with Anxiety Disorders.

Due to the design of the study, we will not be able to provide any individualised feedback to participants about their health condition, saliva sample, or DNA. However, researchers will be providing everyone who participates with study updates.

Our research team greatly value the time and effort that you give to research.

## 8 What are the possible risks and disadvantages of taking part?

You may feel some of the questions in our survey are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question or stop immediately.

Should you become uncomfortable or distressed, and wish to speak to someone about this, you may contact:

- Lifeline (offer free, confidential psychological support:13 11 14),
- Beyond Blue (provide free, confidential psychological support: 1300 22 4636).

If your responses to our online survey questions indicate 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 you have questions about the study you can contact our researchers via phone or email.

- Free call: 1800 257 179
- Email: lwa@qimrb.edu.au

## 9 Will I be contacted again about this study?

If you choose to participate, we may contact you to clarify some of your responses or invite you to be part of future studies.

Choosing to participate in the current study does not mean that you will be re-contacted. If we do contact you about a follow-up study, you can choose not to participate and it will not impact your participation in the current study in any way.

## 10 Is it confidential?

Yes. 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 personal details and other data using this number is restricted to selected members of the QIMR Berghofer Medical Research Institute research team. All information about you will be stored securely, with access restricted to members of the research team.

Any Medicare Benefits Schedule (MBS) 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 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. We may also match your personal data against other health registers. Before any future work proceeds, it will be subject to approval by the relevant ethics committees.

Your genetic information and some of the questionnaire information (but no names, other personal details) may eventually be contributed to an international genetics data repository. Information in the database would only be available to researchers who are approved to study how genes influence health conditions. These scientists will never know your name or any other personal information.

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 individual participants.

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 the information you provided.

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.

## 11 What will happen to my saliva sample?

**This Study:** We will use your saliva sample to extract 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 an Anxiety Disorder and some people do not, or why some people respond to a treatment while others don't.

Your saliva 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 will be stored separately. Linking your personal details with your saliva sample or DNA using the barcode is restricted to members of the QIMR Berghofer research team.
We may send part of your saliva sample or DNA to another laboratory (which may be overseas) for processing or analysis. If this occurs, that sample would only be labelled with a number, and would be 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 would be destroyed.

**Future Studies:** We would like to store your saliva sample 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 saliva and/or DNA samples. In the future, researchers at this and other medical and research centres may use your samples to learn about other 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 indefinitely.

## 12 Will I be given the results of the research project?

The information collected in this study will not be analysed at an individual level and there will be no results specifically about you.

We will be sending updates about our research findings, which will include group level results.

Your information will be used for research purposes and you will not be given any clinical results from this study. 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.

Please note that genotype results are for research purposes only. They are not intended and validated for clinical purposes and will not be returned to participants.

## 13 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.

## 14 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 by contacting the Project Co-Coordinator by phone 1800 257 179 (freecall) or email lwa@qimrb.edu.au. These contact details will be listed on your correspondence with the project team. If you do withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form; the research team will provide this to you.

If you do withdraw from the project, information would only be retained to comply with laws relating to information privacy and the retention of public records and related legislation. You should also be aware that data collected up to the time you withdraw will form part of the research project results, though you will not be able to be identified from this information. However, none of the information you have provided will be used for the study after you withdraw.

## 15 What if I have questions?

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:

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| **Name** | Richard Parker |
| **Position** | Project Coordinator |
| **Telephone** | 07 3362 0297 or Freecall 1800 257 179 |
| **Email** | richard.parker@qimrb.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:

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| **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@qimrb.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.

## 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, saliva sample and DNA that you donate to the study.

**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 understand my involvement is strictly confidential and no information about me will be used in any way that reveals my identity.
- I understand the information I provide will be stored in a data file using an ID code number and that my name and contact details will not be stored in this file.
- I understand reports and publications from the study will be based on de-identified information and will not identify any individual person taking part.
- I understand my decision on whether or not to take part in the Living with Anxiety Study will not disadvantage me or affect my future health care in any way.
- 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 there will be no cost to me for participating in the study.
- I understand I may be approached again to participate in future studies but I am under no obligation to do so.
- I understand that I will be able to save an electronic copy of this document to keep.
- I understand that if I donate a saliva sample it will be used to help discover genes that may influence the risk for, and treatment of, Anxiety Disorders, using the latest technologies available for genotyping, sequencing and gene-expression analysis.
- I understand that analyses of data collected during this study may include analysis of subgroups of participants based on characteristics such as Gender, Age, Ethnicity, Urban vs Rural locations but that these subgroups analyses will not identify any individual person taking part.
- I understand that this research may have some commercial potential in the future, and that my questionnaire, saliva sample and DNA information will be stored and may be considered for use in future research that may or may not be related to this research project. I understand that use of this kind can only be undertaken subject to separate review by the QIMR Berghofer Medical Research Institute Human Research Ethics Committee. I understand that if I provide questionnaire data and a saliva sample they will be used freely for these purposes.
- 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.

☐ Agree and continue to survey *[Date and time automatically recorded]*

*This research is being conducted under the supervision of Professor Sarah Medland from the Mental Health and Neuroscience Research Program, QIMR Berghofer Medical Research Institute, and has been approved by the QIMR Berghofer Human Research Ethics Committee (**QIMRB-HREC approval P3910**).*