APGS

AUSTRALIAN PARKINSON'S
GENETICS STUDY

Information for Participants

Please read the following Information Sheet.

1. What is the purpose of the study?

A person's risk of Parkinson's disease (PD) has a hereditary component. Understanding how genes are implicated in the disease process can provide insights into the molecular mechanisms leading to Parkinson's onset and progression and highlight new therapeutic targets for more effective treatments.

The Global Parkinson's Genetics Program (GP2) is an ambitious program to study the genetics of >150,000 volunteers worldwide to understand the genetic risk factors of PD further. There is still much to learn about PD, and the path to further understanding requires the participation of hundreds of scientists and clinicians and thousands of patients from all backgrounds. More information about GP2 is available at https://gp2.org/

The purpose of the Australian Parkinson's Genetics Study (APGS) is to establish a national PD cohort study of >6,000 participants with PD to advance understanding of the epidemiology, phenotypic and clinical diversity, and genetic risk factors of PD in Australia. We are **also recruiting people without PD** as controls. In epidemiology and genetics research, case/control studies compare groups of people with a different outcome (e.g., with and without PD diagnosis) but who are otherwise similar, for instance, in terms of their age, background, and geographical location. This enables researchers to identify variables associated with the outcome of interest.

Since APGS is a study member of GP2, participants will also contribute to the largest study of PD genetics ever undertaken to date. In the long run, we hope that the findings of this study will result in knowledge that informs the development of new therapies to prevent, treat and delay PD in Australia and around the world.

2. Who can participate?

Persons of any age or gender who have a current diagnosis of Parkinson's disease and live in Australia during participation. They must be able and willing to provide informed consent to participate in the study.

Persons aged 45 and older who do not have a diagnosis of Parkinson's disease can participate in the control/reference group. They must also live in Australia during participation and be able and willing to provide informed consent to participate in the study.

3. What does participation involve?

Participation involves consenting to participate in the project, providing your contact details and answering a questionnaire about your family history, medical history, lifestyle, and environmental risk factors. Altogether, the questionnaire should take about 20 minutes.

Based on your answers to the questionnaire, you may be asked to donate a saliva sample and invited to answer a follow-up questionnaire.

Participation also involves consenting to the storage of your questionnaire and genetic information in a secure data repository for future use. This information may be stored indefinitely and pooled together with similar data from other participants. To see how your privacy is protected, please read *Section 8 - 'Is it confidential?'*

If you are asked to provide a saliva sample, we will send you a collection pack including a specialised collection container to collect the sample. You will be asked to return this sample via *Australia Post* to our laboratory, at no cost to you.

If you donate a sample, we will extract DNA from your saliva to investigate genetic factors that increase PD risk and/or influence disease prognosis and treatment response. We will compare your DNA against people with PD or compare DNA of PD patients who experience a particular symptom against those who do not.

4. Do I have to give a DNA sample?

To participate in this study, you may be asked to provide a saliva sample, as explained in the paragraph above. Providing a sample can be done in your own home.

5. What is in it for me?

While 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 investigating. Future medical or scientific discoveries may come from the research in which you participate, and, in turn, help improve the available treatments and outcomes for all people with PD. Many participants value the unique contribution that they can make to research.

Due to the specific sample design of the study, we will not be able to provide any individualised analytical feedback to participants about their health conditions, biological sample, or DNA. However, researchers will be providing everyone who participates with a newsletter. In this *newsletter*, we will give you information about the progress and outcomes of this study, as well as that of several other relevant studies. Our research team values the time and effort that you give to research.

6. Are there any risks?

Researchers acknowledge that being invited into this research study may be a sensitive issue for you and may, therefore, cause you some discomfort. We would like to restate that we currently do not have any information about you.

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 can skip it and go to the next question, or you may stop immediately.

If you have any questions or concerns about this research study, you may telephone the Project Coordinator, Kerrie McAloney on 07-3362-0192. You may also use our free call number: 1800-257-179 or email us at pd.genetics@qimrberghofer.edu.au. If you have any concerns or complaints regarding the conduct of this study, you may contact the Chairperson of the QIMR Berghofer Medical Research Institute Human Research Ethics Committee (QIMRB HREC) via the Secretary on Tel: 07-3362-0117 and quote reference number P3711.

7. Will I be contacted again about this study?

We plan to extend this study and may seek to re-contact some of the participants in the current study.

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

8. Is my data confidential?

Yes. All information and data collected for the study remains confidential in accordance with The Australian National Health and Medical Research Council (NHMRC) Human Research guidelines and the Australian Privacy Act.

Your personal details, questionnaire data, biological sample and genetic data will all be stored separately. Your individual questionnaire, biological sample and genetic data files will have a number assigned to it, not your name. Your name and personal details will continue to be stored on file at QIMR Berghofer but will be stored separately from, and not linked with, your questionnaire information, biological sample and genetic data. The only link between your data and your personal details is your participant identification number (meaning your sample is potentially re-identifiable). Linking both your personal details and data file using this number is severely restricted to members of the QIMR Berghofer research team.

Results of this research study may be presented in scientific papers in medical literature, or in public talks, but your identity will never 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 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 contact the Project Coordinator, Richard Parker on 07-3362-0297. You may also use our free call number: 1800-257-179 or email us at pd.genetics@qimrberghofer.edu.au 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 study.

9. What will happen to information about me?

The researchers will store your personal, questionnaire and genetic information indefinitely at QIMR Berghofer Medical Research Institute. The reason why we need to store this information indefinitely is that it will 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 or other personal details) will be put into the GP2 international 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.

10. What will happen to my biological and DNA samples?

This Study: We will use your biological (saliva) 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 Dementia and some people do not. The research team will also investigate why some people have differing caregiver experiences.

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 only to members of the QIMR Berghofer research team.

We may decide 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 identifying you will be sent to or accessible by the other laboratory. Any sample remaining after processing or analysis by the other laboratory will be returned to QIMR Berghofer Medical Research Institute for indefinite storage.

Future Studies: We would like to store your biological and/or DNA samples for a long time for use in future research studies that may or may not be directly related to this study.

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.

11. Who are the researchers?

This study is being conducted by the following researchers at QIMR Berghofer:

- Dr Miguel E. Renteria
- Professor Nicholas G. Martin
- Professor Sarah E. Medland
- Dr Penelope Lind
- Dr Philip E. Mosley

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 the research. You can withdraw your consent by contacting the Project Coordinator by phone 1800 257 179 (free call) or email pd.genetics@qimrberghofer.edu.au.

13. What if I have questions?

You can call or email us. Our Free call number is 1800 257 179. Our email address is pd.genetics@qimrberghofer.edu.au. We are happy to answer any questions you have before you agree to participate and at any time throughout the study.

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

Yes - proceed to consent page

No - I choose not to participate / I am not eligible

Consent

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 you provide us.

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

- I voluntarily give my consent to participate in the research study ***'Australian Parkinson's Genetics Study'*** as described in the Information Sheet, including the provision of a saliva sample to be used for DNA testing, to learn more about how genes and environment affect health and behaviour.
- I acknowledge that the nature, purpose, risks, and contemplated effects of this research study, especially as far as they affect me, have been fully described to my satisfaction by the Information Sheet.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that I will be able to save an electronic copy of this document to keep.
- I acknowledge that my saliva sample and DNA, which I choose to provide (but NOT my name or address) may be made available to other medical researchers studying health and behaviour in the future, subject to review by the appropriate research ethics committees.
- I acknowledge that my saliva sample and DNA will be stored indefinitely and may be considered for any use in the future related projects, including uses that are unrelated to this study, subject to review by the appropriate research ethics committees.
- I acknowledge that my data from this follow-up study will be stored indefinitely and may be considered for any use in the future related projects, including uses that are unrelated to this study, subject to review by the appropriate research ethics committees.
- I acknowledge that my genetic information and some of my questionnaire information (but not my name or any other personal details) will be put into the Global Parkinson's Genetics Program (GP2) international data repository to study the role of genes in PD. Information in the database will be available only to researchers from around the world, subject to review and approval from Australian Parkinson's Genetics Study researchers.

- I understand that my involvement in this research study may not be of any direct benefit to me and that I may withdraw my consent at any stage without affecting my rights or the responsibilities of the researchers in any respect.
- 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.

This project has been reviewed and approved by the QIMR Berghofer Medical Research Institute Human Research Ethics Committee (QIMRB-HREC P3711). If you have any concerns or complaints regarding the conduct of this study, you may contact the Chairperson of the Ethics Committee (QIMRB-HREC) via the Secretary on Tel: 07-3362 0117 and quote reference number P3711.

Yes – I agree to participate	No - I choose not to participate

The participant may have cognitive impairment resulting in reduced capacity to give informed consent. In this case consent may be indicated by a person responsible for the participant, this is the participant's legal guardian, or person or organisation authorised by law.

As the Person Responsible for the Participant, I agree to participate	As the Person Responsible for the Participant, I choose not to participate

Participant Questionnaire

1. Participant Details

Please provide your details below. We will use these to confirm your identity and update our records with any changes.

Title:

First Name:

Middle Name:

Last Name:

Date of Birth:

Sex:

Email:

Phone Number:

Residential Address

Country:

State:

Postcode:

Full Address:

☐ Postal address same as residential?

Do you require any help to complete this survey?	☐ No. I am completing the survey myself. ☐ Yes, a caregiver, friend or family member is assisting me. ☐ Yes, a caregiver, friend or family member is completing the survey on my behalf.

Thank you for agreeing to participate in this study.