The Australian Genetics of Parkinson's Disease 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. Genes also influence disease prognosis and a patient's treatment response. Large scale studies investigating genetic risk factors increase our understanding of the disease process and may help identify novel and more effective treatments. However, these studies need the participation of large numbers of people who have been diagnosed with the condition. So far, studies on PD genetics have lagged behind those on other common conditions (such as heart disease, cancers). Therefore, we are trying new ways to contact as many people as possible who have or have had treatment for PD, and one way of doing this is to approach people who have previously reported they have been treated for PD. In the past, we have taken this approach for other medical conditions and had a good response.

We hope that you will participate in the study. Our aim is to find new ways to improve treatment for PD, and also to improve the lives of patients and their families.

2. Who can participate?

For this study we need to recruit both men and women who have been prescribed dopaminergic and/or anticholinergic agent medications.

3. What does participation involve?

If you choose to participate in the study, you will need to complete the consent form, provide your contact details and answer a questionnaire about your disease diagnosis.

You will be asked to consent 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?'* We will also ask you for permission to access the genetic information you have previously given QSKIN.

Some details of your medical history that would be helpful to the project investigators (like how many prescriptions you may have had for various medication) would be hard for many people to remember. Therefore, we will ask for your permission to access your 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 complete Pharmaceutical Benefits Scheme (PBS) data. The consent form will be sent securely to *Services Australia* who 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 is not necessary to participate in the other parts of this study.

The questionnaire component will consist of a handful of modules, each about a different dimension of PD, such as symptoms, medical history, treatment effectiveness, lifestyle and environmental factors, etc. Altogether the questionnaire should take about 15 minutes.

If you complete the online survey, we will use this information along with your existing genetic data to investigate genetic factors that increase PD risk and/or influence disease prognosis and treatment response. For example, we will compare DNA from people with PD against a control group who do not have this condition, or compare DNA of PD patients who experience a particular side effect against those who do not.

4. Do I have to give a DNA sample?

No. But because this is a genetic study we do need genetic information. We can get this information, with your permission, by using the DNA blood or saliva samples you have given the QSKIN study in the past.

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 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 condition, 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, Richard Parker on 07-3362-0297. You may also use our free call number: 1800-257-179. 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 it 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, and genetic data will all be stored separately. Your individual questionnaire, 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 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.

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.

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 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 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 <u>not</u> your name, other personal details, Medicare or PBS data) may eventually be put into an international genetic 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.

11. Who are the researchers?

This study is being conducted by the following researchers:

- Dr Miguel Renteria, QIMR Berghofer Medical Research Institute.
- Dr Penelope Lind, QIMR Berghofer Medical Research Institute.
- Prof Nick Martin, QIMR Berghofer Medical Research Institute.

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 by contacting the Project Coordinator by phone 1800 257 179 (free call) or email pdgenetics@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 pdgenetics@qimrberghofer.edu.au. We are happy to answer any questions you have before you agree to participate and also 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 and DNA that 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 Disease Genetics Study' as described in the Information Sheet to learn more about how genes and environment affect health and behaviour.

□ I acknowledge that the nature, purpose 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 acknowledge that information from this study will be stored indefinitely and may be considered for use in the future related projects, including uses that are not directly related to this study, subject to review by the appropriate research ethics committees.

□ I voluntarily give my permission for any of my genetic information collected from blood/saliva/cheek cells in the QSKIN study to be linked to the information from this current study.

□ I voluntarily give my permission for any of my non-genetic (phenotypic) information collected from the QSKIN study to be linked to the information from this current study.

□ 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 - proceed to consent page	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

Pharmaceutical Benefits Scheme (PBS) Claims Information

On the next page, you will be asked to fill out a consent form authorising the researchers to access your complete Pharmaceutical Benefits Scheme (PBS) data as outlined in the consent form. The PBS collects information on the prescription medications you have filled at pharmacies. The consent form is sent securely to *Services Australia* (formerly known as the Australian Government Department of Human Services) which holds this information confidentially.

If you do provide your consent for access, we will request the following information from *Services Australia*:

Pharmaceutical Benefits Scheme (PBS)

- Date of supply (date the prescription was supplied by the pharmacy)
- Date of prescribing (date that the prescription was prescribed by a medical practitioner to a patient)
- PBS item code (item numbers reflected in the Pharmaceutical Benefits Scheme)
- PBS item description (item description as noted in the Pharmaceutical Benefits Scheme Book)
- Patient category (concessional status of the patient at time of supply)
- Patient contribution (dollar amount paid by the patient)
- Net benefit (dollar amount paid to the pharmacy by *Services Australia*)
- Scrambled prescriber number (number unique to the doctor who prescribed the PBS item, but scrambled so that the doctor cannot be identified)
- Pharmacy postcode (postcode of the pharmacy where the prescription was dispensed)
- Form category (original or repeat prescription)
- ATC Code (the code allocated by the World Health Organisation Collaborating Centre for Drug Statistics Methodology)
- ATC Name (the group the drug falls under in the Anatomical Therapeutic Chemical (ATC) classification system)

A sample of the information that may be included in your PBS claims history:

Date of supply	Date of prescribing	PBS item code	Item description	Patient category	Patient contribution (this includes under copayment amounts)	Net Benefit (this includes under copayment amounts)	Scrambled Prescriber number*	Pharmacy postcode
06/03/09	01/03/09	03133X	Oxazepham Tablet 30 mg	Concessional Ordinary	$5.30	$25.55	9999	2560
04/07/09	28/05/09	03161J	Diazepam Tablet 2 mg	General Ordinary	$30.85		9999	2530

* Scrambled Prescriber number refers to a unique scrambled prescriber number identifying the doctor who prescribed the prescription. Generally, each individual prescriber number will be scrambled and the identity of that prescriber will not be disclosed.
** Under co-payments can now be provided for data after 1 June 2012

Form Category	ATC Code	ATC Name
Original	N05 B A 04	Oxazepam

Repeat	N05 B A 01	Diazepam

Consent for this section is not required for overall study participation. If you do not wish to provide consent for PBS data access, simply select "I do not wish to consent to release PBS Claims Information" below. You will still be eligible to participate in all other aspects of the study.

Information Supplied by *Services Australia* (formerly known as the Australian Government Department of Human Services)

APP 5 – PRIVACY NOTICE

Your personal information is protected by law (including the Privacy Act 1988) and is collected by *Services Australia* for the assessment and administration of payments and services.

Your information may be used by *Services Australia* or given to other parties where you have agreed to that, or where it is required or authorised by law (including for the purpose of research or conducting investigations).

You can get more information about the way in which the department will manage your personal information, including our privacy policy at servicesaustralia.gov.au/

- ❍ Proceed to consent form for PBS claims information
- ❍ I do not wish to consent to release PBS claims information. Proceed directly to questionnaire

Save and Continue

Pharmaceutical Benefits Scheme (PBS) Claims Consent

Consent to release of Pharmaceutical Benefits Scheme (PBS) claims information for the purposes of the 'Australian Parkinson's Disease Genetics Study'.

Important Information

Complete this form to request the release of PBS claims information to the 'Australian Parkinson's Disease Genetics Study'. Incomplete forms may result in the study not being provided with your information.

By indicating my consent, I acknowledge that I have been fully informed and have been provided with information about this study. I have been given an opportunity to ask questions and understand the possibilities of disclosures of my personal information.

Title: *Prefilled information from previous data entry*

Family name: *Prefilled information from previous data entry*

First given name: *Prefilled information from previous data entry*

Other given names: *Prefilled information from previous data entry*

Date of birth: *Prefilled information from previous data entry*

Residential address: *Prefilled information from previous data entry*

Postal address: *Prefilled information from previous data entry*

Medicare card number (first nine digits, no spaces):
<text box>

☐ I declare the information on this form is true and correct

Please indicate below your intent:

☐ I authorise *Services Australia* (formerly known as the Australian Government Department of Human Services) to provide my Pharmaceutical Benefits Scheme (PBS) claims history for the period *<01/05/2015>* to *<30/04/2020>* to the "Australian Genetics of Parkinson's disease" study

Save and Continue