New Zealand Brain Research Institute

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New Zealand Parkinson's Environment and Genes Study (NZPEGS)

Participant Information Sheet for Control Participants

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Study Site: New Zealand Brain Research Institute (NZBRI), Christchurch

Ethics committee ref: 2022 EXP 11833

We would like to invite you to be a "Control" participant for our study. You have been identified through sampling of the New Zealand Electoral Roll for someone of your age and sex.

Our study aims to improve our understanding of Parkinson's disease in New Zealand. Controls play a vital role in our research, by providing a comparison group that does not have Parkinson's. Information provided by Controls will allow us to identify factors that might cause Parkinson's or identify changes that might be due to Parkinson's itself rather than due to the healthy ageing process that we all share. Thus, our Controls need to be free of Parkinson's and other brain conditions, as outlined in our exclusion criteria (see below).

Our study aims to investigate the genetic and environmental exposures associated with Parkinson's. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We are available to answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

The study is nationwide and designed primarily as an online study. Data collection will be through a series of online questionnaires, followed by an online interview. There is the option of completing the study on paper. If you agree to take part in this study, you will be asked to sign the Consent Form. This can be done by providing eConsent online or by completing the attached consent form and returning it to us.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Your participation is voluntary, your choice. You are able to withdraw at any time without having to give a reason. You will not be disadvantaged in any way for withdrawing from the study.

WHAT IS THE PURPOSE OF THE STUDY?

We know that genetic and non-genetic factors underlie the development of Parkinson's in most people. These factors have not previously been studied in New Zealand.

For this project, we aim to obtain data on genetic risk factors, occupational and environmental exposures, and other medical and life-style factors that you have experienced throughout your lifetime. This will allow us, through comparison with responses from people with Parkinson's, to identify the key factors involved in the development of Parkinson's within the New Zealand population.

HOW IS THE STUDY DESIGNED?

We aim to recruit up to 1000 people with Parkinson's and 500 population controls (randomly selected from the electoral roll) for the study.

Data collection is divided into four phases. Phase 1 is a set of screening questions to ensure you do not have Parkinson's or a related disorder.

Phase 2 involves online questionnaires that should be completed over time (e.g. weeks to a month). We do not expect or suggest you complete all the questionnaires in one sitting. The expected completion time for each questionnaire is indicated within the online portal.

The questionnaires will cover topics such as your occupation history, environmental exposures you have encountered through your work or non-work activities, your medical history, lifestyle, and diet patterns throughout life, current medications, and questionnaires about aspects of general wellbeing.

Phase 3 involves a study pack being sent to you at home. The pack will include a saliva collection kit from which we will extract a DNA sample, scratch 'n' sniff booklets to allow for the assessment of your sense of smell, and if requested, a tape measure to allow for the measurement of your hip and waist circumference. You will receive a postage paid courier bag to return the saliva sample, smell test and tape measure to us.

Phase 4 involves an online interview with study staff conducted using a video calling service such as Zoom. We will complete some movement assessments, and memory and thinking tests, which will be recorded for offline analysis. Your online questionnaires will be reviewed prior to the interview and any missing information collected.

All data and samples collected from you will be stored securely. Access to the data and samples will be restricted to study personnel only. Coded (de-identified) data will be used in all analyses.

WHO CAN TAKE PART IN THE STUDY?

To be eligible, Control participants need to be free of the following neurological (brain) conditions;

- Any form of dementia (Alzheimer's disease, frontotemporal dementia, vascular dementia)
- Any form of parkinsonism (e.g. Parkinson's disease, multiple system atrophy, progressive supranuclear palsy, corticobasal syndrome, medication-induced parkinsonism (generally through the use of antipsychotic medications), or vascular parkinsonism)
- Multiple sclerosis
- Motor neuron disease
- Epilepsy
- Essential tremor
- Stroke
- Ataxia (reduced muscle control)
- Dystonia (involuntary muscle activity causing repetitive or twisting movements)

If you would like to participate but do not have a suitable device or internet connection, we can provide paper copies of the questions and complete some aspects of the study over the phone. Please contact us to arrange this.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Study Phase	**Data to be Collected**
Phase 1 – Screening questionnaire	You will be asked to complete a short questionnaire to make sure you do not have Parkinson's or a related disorder. ~3 minutes completion time Answers to these questions may trigger a clinical review with our neurologist, this will be required to continue with the study.
Phase 2 - Online questionnaires Questionnaires will be grouped into blocks, each block should take no longer than 30-40 minutes to complete We suggest you complete these over time (weeks to a month) rather than in one sitting	Customised and standard questionnaires will be used to collect data about your - Work and non-work-related environmental exposures - Residential addresses to identify rural vs urban locations - Hobbies - Lifestyle factors such as physical exercise and diet - Medical history and general health - Mental health and other neuropsychiatric

	symptoms (depression, anxiety, apathy) - Movement - Sleep - Pain
Phase 3 - Study Pack We will send you a study pack to assist data collection	Pack will include; - A saliva collection kit for DNA, to be returned to us. ~10 minutes collection time. - Scratch 'n' sniff booklets to assess sense of smell. Answers entered online or completed within the booklet, ~20 minutes collection time. - If required, a tape measure for measuring your waist and hip circumference. ~5 minutes collection time. - *'NZPEGS Future DNA Research'* information sheet and consent form. Supplied for consideration.
Phase 4 - Online interview The interview will be recorded	Interview will include; - Review of answers given to online questionnaires, and filling in of any information gaps. - Movement assessments. ~15-20 minutes collection time - Memory and thinking assessment. ~10-15 minutes collection time. - Discussion of the '*NZPEGS Future DNA Research'* information. ~15 minutes

We will aim to complete the data collection within a three-month period.

WHAT WILL HAPPEN TO MY SALIVA SAMPLES?

Your saliva sample will be used to generate genomic data. Genes are the basic 'instruction book' for the cells that make up our bodies. Genes are made out of DNA, and all of the DNA in each cell is called the genome. Although our DNA is very similar to each other, your genomic data is entirely unique.

Upon receipt of your saliva sample, it will be securely stored at the New Zealand Brain Research Institute. Saliva samples will be batch processed for the extraction of DNA in the laboratory of Prof. Martin Kennedy, Dept. of Pathology, University of Otago, Christchurch. Extracted DNA will be stored within Prof. Kennedy's lab until genetic analysis is complete. These analyses will be completed either at the National Institutes of Health, Bethesda, USA (if consented to) or within New Zealand.

You choose if your DNA is sent overseas for analysis.
Your samples will be labelled with your unique study identification number.

Your DNA will be screened for a large number (over one million) of locations known to have variation, with a focus on Parkinson's and other brain-specific genetic variations. This type of analysis is known as a genome-wide association study or GWAS. We will also be carrying out detailed sequencing of the GBA gene, which is the gene most commonly associated with an increased risk of Parkinson's.

Cultural Statement

You may hold beliefs about a sacred and shared value of DNA and the information contained within it. The cultural issues associated with sending your DNA overseas and/or storing your DNA should be discussed with your family/whānau as appropriate. There are a range of views held by Māori around these issues; some iwi disagree with storage of DNA citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, as an individual you have the right to choose.

You can choose to have a karakia (blessing) at the time of sample disposal. This will occur for containers used to collect your saliva sample and for DNA kept in New Zealand but not for any portion of your sample that is sent overseas.

You will have the opportunity to contribute your DNA to *'future DNA research'* There is a separate information sheet and consent form for this, which will be provided to you during your participation in this study.

ONGOING RESEARCH RELATED TO THIS STUDY

You have the option of opting into additional future research.

Contribution of Data to International Studies now and in the Future

We are collaborating with researchers from around the world through the Global Parkinson's Genetics Program (GP2) to study the genetics of Parkinson's. Research participants within GP2 includes people with and without Parkinson's. You can find more information about GP2 and the researchers leading the program at https://www.parkinsonsroadmap.org/gp2/. Researchers within the GP2 network will help us with this project by completing some of the genetic studies for us. This will involve DNA being sent to the USA.

There may also be opportunities for our participation in other collaborations in the future. You can choose if your data is contributed to GP2 or similar studies in the future.

Data contributed to international studies will be coded and securely stored, either on local (in other countries) servers or in the cloud. Access to the data will be restricted to approved researchers.

Continuing Data Collection

We would like to repeat some of the questionnaires used in this study with you again on an annual basis. This type of longitudinal research programme is very powerful in understanding how the disorder progresses over time. This data in combination with the extensive genomic data we will be generating from you will provide important

information that will help increase our knowledge of the role of genetics on disease progression.

Future Research Using Your Information

If you agree, your coded information may be used for future research related to Parkinson's and other neurological and neuroscience research. Use of your data in future research is optional, with your choice indicated in the consent form.

This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your information may be shared widely with other researchers or companies. Your information may also be added to information from other studies, to form much larger sets of data.

You will not get reports or other information about any research that is done using your information.

Your information may be used indefinitely for future research, unless you withdraw your consent. However, we will be unable to withdraw your information from studies that are already complete or underway.

RETURN OF RESULTS OF CLINICAL SIGNIFICANCE

Genetics

It is possible that the genetic analyses completed as part of this study will identify carriers of genetic mutations known to cause Parkinson's, even if you are currently showing no signs of the disorder. We know that ~10% of Parkinson's cases will have a solely genetic cause. If you consent to receiving this information, we will let you know if you have been identified as a carrier of a genetic mutation known to cause Parkinson's. We will also inform your GP and outline appropriate actions that can be taken. This could involve the confirmation of the mutation via clinical genetic testing (we are using research methods) and genetic counselling for you and your family.

Depending on the mutation identified, there may be important information on the future risk of Parkinson's for your siblings or offspring.

The return of this data may take some time and could be as long as 2-years after your sample collection.

Questionnaire Results

Some of the questionnaires included in the research may identify areas of your health that require follow-up with your GP. If you consent to receiving this information, we will let you know if your responses on the *mood* questionnaires indicate that follow-up with your GP is recommended. We will also directly inform your GP of these results.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is

currently very small, but may increase in the future as people find new ways of tracing information.

Your coded information, with your permission, will be sent overseas. Other countries may have lower levels of data protection than New Zealand. There may be no New Zealand representation within overseas organisations, which make decisions about the use of your information. There is a risk that overseas researchers may work with information in a way that is not culturally appropriate for New Zealanders.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

It is unlikely that there will be any direct benefit to you from participating in this study. There may be benefits for people in the future through education and behaviour change subsequent to our identification of contributors to Parkinson's in New Zealand.

WILL ANY COSTS BE REIMBURSED?

We do not anticipate any costs to be incurred by you as a participant in the study. No payments will be made for your participation.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study, the researchers will record information about you and your study participation. This includes the results of the questionnaires used in data collection and the data generated from the DNA analyses associated with this study.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Your identifiable information will be known by the following groups;

- Staff directly involved in the collection of data for the study.
- Staff and students involved in the scoring of movement and memory recorded during the online interview.
- Ethics committees, or government agencies from New Zealand or overseas, if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.
- Your usual doctor (GP), if the DNA analyses indicate you have a genetic mutation able to cause Parkinson's or the answer to certain questionnaires indicate follow-up with your GP is appropriate.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any reports generated from the study. Instead, you will be

identified by a code. Researchers will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The following groups may have access to your coded information, which may be sent and stored overseas:

- Staff and students completing analyses on collected data, including DNA.
- International researchers completing analyses within the GP2 network or other similar international studies, if you consent to your data being included in these initiatives.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Online Interviews

The online interview will be recorded to allow for data checking and the offline scoring of the movement, memory and thinking assessments.

At the end of the study, the full recordings will be deleted, however we will retain the movement and memory test segments. These segments will include your face and as such will be identifiable. Video recordings or still frames from them will not be used in any presentations or publications.

All video files will be saved using your unique study identifier and stored locally on secure networks. Access to the video files will be restricted to only staff and students directly involved in the research project.

Rights to Access Your Information

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

If you have any questions about the collection and use of your information, you can contact our research staff, whose details are located at the end of this information sheet.

WHAT HAPPENS IF I CHANGE MY MIND?

You may withdraw from the study at any time by informing study staff. If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you. If you agree, information and samples collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for your data to be deleted when you withdraw, however, it will not be possible to withdraw data from analyses that have already been undertaken or are in progress.

If you want to withdraw from the study please contact Dr Toni Pitcher, Lead Investigator, phone: 0800 119 814 or email: pegs@nzbri.org

CAN I FIND OUT THE RESULTS OF THE STUDY?

You can choose to receive a plain English summary of the research outcomes. These will be emailed or posted to you at the end of the study. Please bear in mind that it will take some time to complete the study. We have allowed 3-years for the data collection and analysis, so final conclusions will not be available until at least 2025.

WHO IS FUNDING THE STUDY?

The study is funded through a project grant from the Health Research Council of New Zealand.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Southern Health and Disability Ethics Committee has approved this study, under approval number 2022 EXP 11833.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Name: Dr Toni Pitcher, Lead Investigator
Phone: 0800 119 814
Email: pegs@nzbri.org

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

For Māori cultural support contact:

Name: Mrs Kathy Simmons
Phone: 0800 119 814
Email: maorisupport@nzbri.org

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHIC
Email: hdecs@health.govt.nz

Study Personnel

Dr Toni Pitcher, Study PI	University of Otago, Christchurch & NZBRI
Dr Daniel Myall	NZBRI, Christchurch
Prof. Martin Kennedy	University of Otago, Christchurch
Dr Mark Simpson	Auckland District Health Board, Auckland
Dr Alastair Noyce	Queen Mary Hospital, London, UK

Miriam Collins	NZBRI, Christchurch
Catherine Sheat	NZBRI, Christchurch
Prof. Tim Anderson	University of Otago, Christchurch & NZBRI

To participate in the study, please visit https://nzbri.org/pegs/ to complete the consent form and online questionnaires.

If you do not have a suitable internet connection or device but would still like to participate, please contact us at pegs@nzbri.org or 0800 119 814.

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CONTROL PARTICIPANT CONSENT FORM

I have read and I understand the Control Participant Information Sheet for the PEG Study.

I have been given sufficient time to consider whether or not to participate in this study.

I have had the opportunity to use a legal representative, whanau/family support or a friend to help me ask questions and understand the study.

I am satisfied with the answers I have been given regarding the study.

I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.

I know who to contact if I have any questions about the study in general.

I consent to the research staff collecting and processing my information, including information about my health.

I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.

I understand my responsibilities as a study participant as indicated below.

a) Undergo a clinical assessment if screening questions indicate one is necessary for continued participation in the study

b) Complete online questionnaires

c) Provide a saliva sample for DNA

d) Complete an online video interview with study staff

Please answer the questions on the next page

Please circle your chosen answers below

I confirm I do not have a brain condition as listed on page 3 of the information sheet	Yes	No
I consent to my DNA being sent to the USA for analysis. I am aware these samples will be disposed of using established local guidelines for discarding biohazard waste.	Yes	No
I would like a karakia (blessing) at the time of disposal of my tissue that remains in New Zealand.	Yes	No
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed, and used in the study	Yes	No
I wish to receive a summary of the results from the study.	Yes	No
Would you like to receive this summary by:	Email	Post
I would like to know my genetic results related to genes that cause Parkinson's.	Yes	No
I would like to be informed if answers to questionnaires indicate clinical follow-up with my GP is required	Yes	No

Please indicate your GP and Medical Practice, including a phone number or email address, if known:

Future Research

I consent to coded data, including my genomic data, being contributed to the international GP2 programme.	Yes	No
I consent to being involved in the annual completion of some questionnaires to provide longitudinal data.	Yes	No
I consent to coded data, including genomic data, being used for future neurological research studies (national and international).	Yes	No

Declaration by participant:
I hereby consent to take part in this study.

Participant's name:	Date of birth:
Signature:	Date:

Please provide the following so we can contact you about your participation:

Phone number:
Email address:
Postal address (not P.O. Box) for sending out the study pack:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:	
Signature:	Date: