Participant Information Sheet

**What do patients with Parkinson's disease need to know prior to Genetic Testing?**

# Invitation

Thank you for taking the time to consider taking part in this research study. **Please read the following information carefully.** If you have any questions, you can contact us on the email provided ([pdmams@plymouth.ac](mailto:pdmams@plymouth.ac)). You have been selected as an expert because of your experience, expertise, or situation and therefore your insight into this topic is deeply valued.

It is essential that you understand why the research is being conducted and what it will involve before you decide whether to participate.

It is important that you consider carefully whether you will be able to complete the study, which consists of a minimum of 2 and a maximum of 5 online surveys, over a maximum of 10 months. **Taking part in each and every survey is really important for this type of study to make sure that results are meaningful.**

Please take some time with your decision and please do ask if you have any queries or concerns.

1. **Why is this study being done?**

Many new drugs that are being designed to slow down the progression of Parkinson’s disease are targeted at specific genetic variants. There are groups of people with Parkinson’s that have genetic variations that increase the risk of them developing Parkinson’s disease. These people will be needed to take part in drug trials which test the effectiveness of these drugs. Currently, knowing whether an individual possesses one of these genetic variations will not change the way their Parkinson’s is treated, but this could potentially change in the future. This will mean that genetic testing for people will become more common and more readily available. The purpose of this study is to understand how best to present information related to genetic testing in Parkinson’s and which issues that arise from it are of most concern to people with Parkinson’s.

In this study we are inviting people with Parkinson’s, their care partners and clinicians to:

* Find out what they understand around the influence of genetics on Parkinson’s and the role of genetic testing
* Understand the concerns that may arise from genetic testing from the perspective of people with Parkinson’s and their care partners
* Come to an agreement on what information is important for patients and their families to know before deciding whether or not to undertake genetic testing, and how best to communicate that information to them

# This study is a Delphi-style study. What is a Delphi Study?

The aim of this Delphi study is to get a group of experts (you’re one of the experts in this study) to agree upon a number of ideas or questions related to the topic. You have been selected as an expert because of your experience, expertise, or situation and therefore your insight into this topic is deeply valued.

The purpose of a Delphi study is to see whether the experts agree with each other on their scores of particular questions or statements.

Delphi style studies do this by having multiple consecutive rounds where these questions or statements are ranked or voted on. In following rounds, the experts can see what the group collectively voted for and decide to stick to their original score or change their mind. This is repeated until either a consensus is agreed upon, or until the 5 rounds are over (where we have to agree to disagree).

It is important to note that nobody in the group can see another individual’s scores, only the overall results for the group as a whole.

# Why have I been invited to take part?

You have been invited to take part because we believe that your viewpoint will be very valuable to us, due to your knowledge, experience and/or skills. The participants whose views we seek to survey are:

1. People living with Parkinson’s
2. Carers of people with Parkinson’s
3. Clinicians looking after people with Parkinson’s.

The perspectives and opinions of these three groups are incredibly valuable to us to gain an insight of what’s important for people with Parkinson’s to understand before undergoing genetic testing.

# Do I have to take part in the study?

You’re under no obligation to take part in the study and it is completely up to you to decide whether or not to take part. If you decide to take part, you will be given this information sheet to keep and be asked to give consent to confirm that you understand what is involved when taking part in this study. You are free to leave the study at any time and without giving a reason (though that will mean that we cannot use your results).

# What will I be asked to do if I decide to take part?

If you decide to take part in this research study and you are selected to take part, you will be sent an email with a link with the survey invitation. This will take you to the survey website where you will be asked to give consent to take part in the study and then you can proceed to the survey. You will not be permitted to begin the survey without signing the consent form beforehand.

You will have up to 4 weeks to complete each survey**.** You will be able to save your responses and return to complete the survey at a later time if you need to. We will ask you for your email address and phone number, which will enable us to contact you for study reminders in the first round, and to send invitations for the following rounds.

If you take part in the first survey, will ask you to write in your own words about your understanding of the implications of genetics in Parkinson’s disease, your views on what is important to know before deciding to take part in genetic testing.

The research team will analyse everyone’s answers to create a list of priorities for genetic counselling conversations between people with Parkinson’s, their care partners and clinicians.

In the second survey we will ask you to rate how important each item is for genetic counselling conversations. We will analyse your answers to see how much people with Parkinson’s, care partners and clinicians share the same views. We will share these results with you in a third survey and if opinions differ, we will ask you to look at a summary of everyone’s views and ask you to re-rate the item to see whether knowing what others think will change your opinion. We will ask you to complete these questionnaires up to five times in total, or until there is a consensus reached on each question or statement asked.

It is important that you complete every survey. If you miss a survey, we will unfortunately not be able to allow you to continue with the study as you will have missed important feedback from other participants. It is important that you complete the survey within 4 weeks, so that other participants do not have to wait too long for the next stage of the study.

We will send you reminder emails during this time to remind you to complete the survey, if you haven’t done so already and may phone you in the first round. Each survey should take no longer than an hour to complete. There will be 4 weeks between survey closure and the launch of the next survey, to allow the study team to analyse and prepare anonymised feedback.

You will also be given the option to tell us if you cannot answer a question. If this is the case, we will give you the option to explain to us why you were unable to answer it. For example, you can let us know whether you did not have enough information or found the question confusing. This will help us to make the question clearer for the next survey round.

It is extremely important that you consider carefully whether you will be able to complete all rounds of the survey. The success of the study depends on you completing every single survey.

# What are the possible benefits of taking part?

While there is no direct benefit or reward for taking part in the survey, you will be helping us to understand what is important for people undergoing genetic testing for PD to understand, which will benefit future patients and help improve their standard of care.

# Will my taking part in this study be kept confidential?

All information collected about you during the course of this study will be kept strictly confidential. We will store your data using a unique code rather than your name. All information will be handled in compliance with the General Data Protection Regulations (2018).

Your name and contact details (which we will need in order to contact you) will be stored separately from the other information you supply during the study so that you cannot be identified from your study records.

# Privacy Notice for Participants

The University of Plymouth is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Plymouth will keep study data for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the research data you have already provided.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the University’s Data protection Officer.

The University’s Data Protection Officer can be contacted by e-mailing: dpo@plymouth.ac.uk

For more information about research and about general use of data collected for research please refer to:

<https://www.plymouth.ac.uk/uploads/production/document/path/6/6913/Research_Data_Policy.pdf>

# What will happen if I don’t want to carry on with the study?

We hope that participating in the study will not take up too much of your time or be an inconvenience for you. We must stress that this study’s success relies on people continuing to the end. You do however have every right to leave if you wish, with no repercussions and without giving a reason (although we will give you the options of telling us the reason, to help us design better studies for the future). If you withdraw, we shall delete all personal information we hold about you, although we will retain any answers to the questions you have given in an anonymised form. This is because we will be unable to retrieve this information from our database after it has been anonymised.

# Will the study information help with other research projects?

The information obtained is likely to contribute to research into the causes of and future treatment of Parkinson’s, by making it easier to undertake genetic testing in people with Parkinson’s

# What will happen to the results of this study?

After the study is completed, you will be sent a summary of the main findings

The results will be used to help us understand what is important for patients undergoing genetic testing for Parkinson’s to understand and how best to present this information to people.

The results will be published in scientific journals and presented at conferences. We will work with people with Parkinson’s to ensure that the results are publicised as widely as possible.

1. **Who is organising and funding this study?**

This study is being organised and funded by the University of Plymouth.

# Who has reviewed the study?

This study has been designed together with and reviewed by people with Parkinson’s disease.

It was further reviewed by the Faculty of Health: Medicine, Dentistry and Human Sciences Research Ethics Committees at the University of Plymouth.

If you have any concerns or complaints about the Ethical conduct of this study, please contact the Research Administrator, Faculty of Health Research Ethics and Integrity Committee, John Bull Building, Tamar Science Park, Research Way, Plymouth, Devon, PL6 8BU

Email: [FOHEthics@plymouth.ac.uk](mailto:FOHEthics@plymouth.ac.uk)

# Contact for further information

If you have any questions, please contact Fintan O’Brien at pdmams@plymouth.ac.uk.

Study Coordinator: Fintan O’Brien

N6, ITTC Building

Plymouth Science Park

Plymouth

PL6 8BX

**Thank you for taking the time to read this information sheet and for considering taking part in our study – your time is greatly appreciated. We hope to hear from you soon.**