

## Tracking Parkinson's

(PRoBaND: Parkinson's Repository of Biosamples and Networked Datasets)

### Information Sheet for: Relatives of patients with Parkinson's disease

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

This study involves people with Parkinson's disease and their relatives and is being conducted across a network of clinics in the United Kingdom. In the Parkinson's patients, the clinical features of their condition will be recorded carefully and repeated over time. In their relatives, a physical examination and set of scores and questionnaires will be performed, on two separate occasions 3 years apart.

Blood samples will be taken for gene tests.

#### Why have I been invited?

You have been invited because you are related to someone with a diagnosis of Parkinson's disease, and we are undertaking a large study in hundreds of relatives like you.

#### What is the purpose of the study?

The study is designed to improve our understanding of the mechanisms of Parkinson's disease, in particular to explore the variations in Parkinson's disease which are known to occur in the four following areas:

1. Motor features – tremor, stiffness, slowness and poor balance
2. The involvement of memory
3. The degree of improvement with medication
4. The presence of other symptoms including bowel, bladder and blood pressure control.

We think that there are gene variations that explain the different ways in which Parkinson's affects the person with the disease. We know about some genes that are linked to Parkinson's, but this is only in 5% of cases.

To learn more about the genes, and how they increase the risk of Parkinson's disease we would like to study both patients with Parkinson's, and their close relatives (mainly brothers and sisters, occasionally parents or children, but not involving anyone aged less than 18 years).

Information collected will be kept free of personal details according the rules of good clinical practice and data protection. You will be able to keep up-to-date with the study through the study's website ([www.proband.org.uk](http://www.proband.org.uk)).

In addition the results will be presented at the Parkinson's UK research meeting, and other national and local meetings including patient group meetings. Research updates will appear in the Parkinson's UK newsletter.

### **What does taking part involve?**

If you agree to take part in the study, the following assessments will be undertaken:

At the baseline visit, your general medical history and any medications you are taking will be recorded, and we will perform a general physical examination including the nervous system. We will ask you to complete questionnaires relating to depression, sleep, impulsive behaviours (like gambling), bowel habit (whether you are constipated), quality of life, environment issues (e.g. whether you have worked with chemicals) and personality. We will do some memory test and check your sense of smell. A blood sample will be taken for gene testing for Parkinson's disease and longer term storage to support scientific research looking for a marker in the blood stream of Parkinson's disease.

At the second visit, 3 years later, we will update any changes e.g. in your medical history or medication, and we will ask you to repeat most of the questionnaires and we will recheck your memory. You will be given information on the Parkinson's UK Tissue Bank and asked to consider making a donation to the Tissue Bank.

Your General Practitioner will be informed of your participation in the study.

### **Do I have to take part?**

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. You will be asked to sign a consent form to show you have agreed to take part.

You are free to withdraw at any time, without giving reason. This would not affect the standard of care you receive or your future treatment.

**Who is conducting the research?**

The research is being carried out by a group of clinicians in the United Kingdom. The Chief Investigator is Dr Donald Grosset from the Department of Neurology, Southern General Hospital, 1345 Govan Road, Glasgow G51 4TF.

**What are the possible benefits of taking part?**

It is hoped that by taking part in this research, you will be providing valuable information regarding the nature and progression of Parkinson's disease, and you will be contributing to new research linking genetic and biomarker observations to our increased understanding of the condition.

**Who has reviewed the study?**

This study has been reviewed by the national research service West of Scotland Research Ethics Committee 1.

**Does this mean I am going to develop Parkinson's Disease?**

No. Some relatives in this study will come from families where many people have been affected by PD and in those families the risk will be higher than the background population risk. On average relatives of people with PD have an approximately 2 in 100 lifetime risk as compared to approximately 1 in 100 for the general population. The vast majority of relatives who participate in the PRoBaND study will not develop PD.

**Can I receive the result of my tests?**

No. The tests in this study are performed on a research basis and cannot be used for clinical purposes. In exceptional circumstances, there may be a clinical reason to give you the result of the gene testing, in which case we will make the necessary arrangements. If you have concerns about your risk of developing PD we would suggest you talk to your own doctor or to the study doctor and in some situations it may be helpful to see a genetics doctor

### **Can outside bodies like insurance companies access the research tests?**

Coded samples (i.e. without your name) for these tests may be shared with other research groups for analysis. Any information collected during the study will be kept confidential.

We will store the assessment and test results on a secure, confidential database. This will enable us to analyse the information gathered for this research. When this study is completed we will continue to hold the data on our computer. You may ask for your personal information to be removed from this database at any time, in accordance with the Data Protection Act 1998.

### **What will happen if I develop memory problems?**

As this is a long-term study, a few participants may experience memory difficulties. The research team would like to retain the blood samples and personal data collected during the study, and continue to use it confidentially, both for the PRoBaND research project and for approved research projects in Parkinson's disease to which the study will contribute. We are therefore seeking your consent to retain the blood samples and personal data for current and further research after the current project has ended, and this would still apply even if you develop memory problems which in the future would limit your capacity to consent to this.

### **How will you use the blood samples collected?**

We will use the blood samples and data to answer the research questions in the PRoBaND study as well as future major Parkinson's disease research studies. This information will not be linked to your name or other identifiers. The samples will be stored in a central laboratory in Cardiff, with an additional sample stored in European government financed centre in Wiltshire, where your blood cells will be treated to make a cell line which will provide a DNA source which may be used by responsible researchers now and in the future, without having to ask you for more blood samples. The genetic information and samples and data may be used in research (relating to diagnosis and treatments) and for teaching purposes by investigators in the UK and around the world.

They will be able to find out a minimal amount of information about the person who gave the sample so that they are able to do useful research, but we will not send them any details that could be traced back to you. Specifically, we will only send the following information about you with your coded sample: sex, race, year of birth, diagnosis, codes for any other people in your family who gave samples, and relationships of these people to each other. No names, addresses, precise dates of birth, or other information that may personally identify you will be sent.

We will treat your samples and data as a gift for medication research, and there will be no payment to you for treatments or other medical advances arising from the use of your samples and data.

**Will I be contacted in the future after completion of the present study?**

We would like to retain your name and contact details, as well as your status in the study (i.e. relative of a patient with Parkinson's disease). We would like to have this listing so that we could contact you in future if there is an additional research project which you might be willing to take part in, at some point in the future.

**Who has funded the study?**

The study has been funded by the patient's charity Parkinson's UK and the future use of the samples and repository will be administered by a committee which will include representatives of Parkinson's UK and people with Parkinson's.

**What will happen to the results of the study?**

We plan to publish any results in scientific journals. Your name would not be mentioned in any publication. We will make regular reports to funding bodies and to patient groups.

**What will happen to the clinical information?**

The clinical information which concerns any illness you may have and your personal details will be kept in your medical records as usual. An anonymised, coded database holding clinical scores and results of your questionnaires and genetic data, without personal details will be held on research computers. This may be used to support other projects which undertake audit and research into Parkinson's disease.

This will allow the best possible use of your information, in a safe way, and without revealing your name or other personal identifiers, to increase our understanding about the mechanisms of the Parkinson's disease process.

**What happens if I choose not to participate?**

Participation in the study is voluntary. If you decline to take part, this will not affect your current or future treatment in any way.

**What happens if I participate but later withdraw from the study?**

You are free to withdraw from the study at any time. We would like to keep the data and blood samples you have provided up to the point of withdrawal, but if you would prefer them to be removed from the study, we will of course agree to this. The standard of any future care will not be affected by a decision to withdraw from the study.

**If you have any further questions?**

We will give you a copy of the information sheet and signed consent form to keep.

If you would like more information about the study and wish to speak to someone not closely linked to the study, please contact Professor Keith Muir, Southern General Hospital, 1345 Govan Road, Glasgow G51 4TF, Tel No: 0141 201 1100.

**Contacts:**

Margaret Crawford is the Study Co-ordinator, and is based at the Neurology Department, Southern General Hospital, 1345 Govan Road, Glasgow G51 4TF. Tel No: 0141 232 7846. Dr Donald Grosset is the Chief Investigator, and is also based in Glasgow. He can be contacted via Margaret Crawford.

**If you have a complaint about any aspect of the study?**

If you are unhappy about any aspect of the study and wish to make a complaint, please contact the researcher in the first instance but the normal NHS complaint mechanisms is also available to you.

Thank-you for your time and co-operation.