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**Tracking Parkinson’s**

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

Consent at 3 years.

**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 took part, as a brother or sister of a person with Parkinson’s, in the Tracking Parkinson’s study. The study is now completed for relatives, but we would like to share information with you about what we plan to do, when we analyse the results of the research tests. Before you decide you need to understand this information. 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.

As you know, this study involves people with Parkinson’s disease and their relatives and is being conducted across a network of clinics in the United Kingdom. Blood samples are being taken for gene testing and longer term storage to support future research.

**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.trackingparkinsons.org.uk](http://www.trackingparkinsons.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?**

The following assessments will already have been undertaken:

At the baseline visit, your general medical history and any medications you are taking were recorded, and we performed a general physical examination including the nervous system. We asked 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 did a memory test and checked your sense of smell. A blood sample was 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. You will also be asked whether you would like to know about results from the research which might be important to your future health, or that of your family. Please see the section below, ‘Can I receive the results of my tests?’ for more details about this.

We will also look at the results of any brain scans, and take a note of any other medical diagnosis you may have, by looking at your medical records.

After the second visit, there will not be any further visits. However, we will use medical information about you that we obtain from ‘record linkage’. This involves monitoring your health, including any medical diagnosis and treatment you may get, by accessing information which is recorded in your health records (eg. your general practitioner and hospital notes). This is done using a unique identifier, and does not involve using or storing your name in our research files. We will continue to access this information after your study visits are completed, so your participation in the study will continue on a longer term basis.Your General Practitioner will be informed of your ongoing 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, Queen Elizabeth University 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, work in this study is performed on a research basis and will not give you a test result. Any possible research findings need to be confirmed. This work will progress through several stages. In the first stage we are looking at genetic changes that are already known to be linked to Parkinson’s. In the next stage we are looking for any possible new gene changes, which are not yet known about. This work will therefore help to develop NHS gene tests, which may give more information about your condition, and help to estimate the risk of disease to other members of your family.  
  
You can choose in advance whether you wish to be informed about these findings. If you do choose to be informed, we will arrange for you to be given appropriate genetic advice and this may involve a new blood test. This will be discussed with you by your specialist. Currently these types of tests do not lead to any new treatments or change in your current treatment for Parkinson’s, but this is expected to change in the coming years.  
  
**What if you identify a risk factor for another disease unrelated to the original research (“incidental findings”)?**  
We will not carry out a complete genetic screen related to all human diseases, but the large-scale analysis means that a lot of genetic variation may be found in your samples. The tests in this study are performed on a research basis and are not used for clinical care. However, if we find something that may possibly have an impact on your future health or that of your family, and for which there are specific treatments or preventive measures that could help you or your family, we would like to tell you about this. For example, some forms of heart disease (such as heart rhythm problems) can be found with a genetic test which may lead to treatment which will prevent further problems. Similarly, some cancers such as breast cancer can be associated with gene changes. If these are identified then you or other family members may be advised to have detailed screening, to try and identify cancer early. If you have specific concerns about any family health issues we would recommend that you discuss this directly with your doctor. However, sometimes we identify these types of changes on an incidental basis. You can choose whether you wish to be informed about this, in advance. If you do choose to be informed we will arrange for the appropriate guidance and counselling and this will involve a repeat blood test.

**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, Queen Elizabeth University Hospital, 1345 Govan Road, Glasgow G51 4TF, Tel No: 0141 451 5892.

**Contacts:**

Alison Smith is the Study Co-ordinator, and is based at the Neurology Department, Queen Elizabeth University Hospital, 1345 Govan Road, Glasgow G51 4TF. Tel No: 0141 201 2486. Dr Donald Grosset is the Chief Investigator, and is also based in Glasgow. He can be contacted via Alison Smith.

**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.