CONFIDENTIAL

Participant Information Sheet
Version 14: 30-March-2022

Study Title: Vision in Parkinson's disease
Chief Investigator: Dr Rimona Weil

You are invited to take part in a research study at the Institute of Neurology. Before you decide whether to take part it is important for you to understand why we are doing the research and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?
The study aims to improve our understanding of the changes in visual processing that take place in different forms of Parkinson's disease and related disorders and help measure effectiveness of future treatments.

Why have I been asked to participate in the study?
We are inviting people who have received a diagnosis of genetic Parkinson's disease or non-genetic Parkinson's disease as well as people who do not have Parkinson's disease but have informed us of a family history of Parkinson's disease. We are also inviting people who have received a diagnosis of cognitive impairment in association with Parkinson's disease, such as Dementia with Lewy Body disease, or who have Alzheimer's disease. We are also inviting healthy people to take part in the study to act as healthy controls.

Do I have to take part in the study?
No, your involvement in this study is voluntary. Having read this information sheet you should take time to consider your involvement and to discuss this with your family and friends. If you have any questions about the study and what participation will mean for you please ask to speak to the study team. If you decide not to participate in the study this will not affect your clinical care in any way. You may decide to leave the study at any time without giving a reason.

What will I have to do if I take part in the study?
We will ask you to come to the Institute of Neurology at UCL for detailed assessments of your memory and thinking. The assessments are listed below in detail:

History and Examination - 30-45 minutes
You will have a medical assessment and an interview with a member of the research team who will ask questions about how you have been feeling, and about any symptoms you may have been experiencing. They will also ask you for information about your previous health and that of your family and for details of any medications you are taking. They will perform a physical and neurological examination. We would like you to do some walking tests while wearing an accelerometer, which is a small device attached to your waist and / or wrists and legs that measures movement. During this assessment, we will also take a short video of you walking. This video is optional.

Vision testing – 10 minutes
Your visual function will be tested using reading charts.

Smell testing – 5 minutes
We will test your sense of smell using specialised smelling sticks.

Blood sampling – 5 minutes
We would also like to collect a blood sample which will be used in biochemical research into Parkinson's disease and cognitive impairment and for genetic analysis. We will take about 70ml of blood (about 4.5 tablespoons) from a vein in your arm. We may ask your permission to split this into two blood draws over the course of your visit. Taking blood is a safe procedure; there is minimal discomfort when the needle is inserted, and there are small risks of bruising.

The UCL laboratory doing the genetic analysis will code your blood sample, and a number rather than your name will be kept. The link between the code and your name will remain confidential and secure and will only be known by the department undertaking the genetic analysis. Our research team will receive anonymised information only, which means all data will be without a link to individual participants. These anonymised data (without your name) may be shared with other research groups for analyses; this is a common scientific practice. All samples will be managed in accordance with the requirements of the Human Tissue Act (2004).

Questionnaire completion – 10 minutes
During the course of your visit, we will ask you to complete a series of questionnaires assessing various aspects of Parkinson's disease, including your mood, how you sleep, how the motor symptoms of Parkinson's disease affect you. The results of these questionnaires will be coded with a number, rather than your name and your individual answers will not be revealed to anyone outside the study.

Neuropsychology – 60 minutes
You will also have a detailed assessment of your memory and thinking. These assessments will last up to one hour. You will be offered breaks and refreshments during the assessments.

If it is not possible for you to attend the research centre in person for any reason, we may ask you to take part in some parts of the research from home – on the telephone or via an online system.

Vision tests on computer – 30-45 minutes
You will perform some vision tasks on the computer.

Magnetic Resonance Imaging (MRI) scan – 60 minutes
You will also have an MRI brain scan. MRI generates an electronic picture of your brain using a strong magnet instead of an X-ray. Before each MRI scan you will be asked questions to make sure you are happy with having the MRI and that it is safe for you to have the MRI. The scan takes about 45 to 60 minutes. During the MRI, you will lie on your back on a table which will enter the MR machine and you will be asked to remain very still. You may be asked to perform some computer based tests whilst in the MRI scanner. You may view images on a screen and make responses by pressing on buttons on a key pad. If you wish, you will be able to communicate with the study team during the MRI.

You can choose to opt out of the blood test, video, eye examination, MRI or retinal scan and still take part in the study.

Eye examination by an Ophthalmologist – 10 minutes, with 30 minutes to allow eye drops to work.
An ophthalmologist will examine your vision using vision charts. He or she will also use a slit-lamp to examine your eyes in more detail. This is an instrument that uses a light and a low-powered microscope, to give detailed information about the structures of the eye. As part of this examination, and to help with the retinal scan, you may have drops (Tropicamide or phenylephrine) put into your eyes to allow your pupils to dilate, or get bigger. These make it easier for your eye to be examined. These will be required on visits when you have an eye examination and the retinal scan. They may not be needed in some people who have larger pupils, and will not be needed on research visits when eye examination and a retinal scan are not done.

You may wish to bring a relative, carer or partner with you to the assessment as eye drops can cause the vision to become blurred for one to two hours and you will be unable to drive during that time. Some people find it helpful to bring sunglasses as dilating drops can result in feeling dazed in bright light.

Retinal scan – 5-10 minutes
We will use a technique called Optical Coherence Tomography to measure the structures of your retina, the light-sensitive tissue that lines the back of your eye. This is a non-invasive method that uses light waves to take cross-section pictures of your retina.

Use of previously acquired clinical/research information

If you have had neuropsychological assessments and/or MRI scans performed as part of your clinical care or participation in other research studies conducted by the Institute of Neurology, it may be helpful for us to include results from these investigations in this study. We will ask you if you consent for us to use this information. If you chose not to give consent this will not affect your involvement in the study.

The timetable for the study is shown below:

PROCEDURE		
	AM	**PM**
Taking of consent	✔	
Medical history and examination	✔	
Vision testing	✔	
Smell testing	✔	
Blood sample	✔	
Questionnaires	✔	
Neuropsychology	✔	
Vision tests on computer		✔
MRI scan		✔
Eye test by ophthalmologist		✔
Retinal scan		✔

During the Covid-19 pandemic, we have adjusted the timetable for the study, to allow some aspects to be performed remotely, allowing shorter study visits. During this time, the timetable is shown below:

PROCEDURE		
	Remote aspects	**Face to face visit**
Taking of consent	✔	✔
Medical history	✔	
Examination		✔
Vision testing		✔
Blood sample		✔
Questionnaires	✔	
Neuropsychology	✔	

Vision tests on computer		✔
MRI scan		✔
Eye test by ophthalmologist		✔
Retinal scan		✔

There will be breaks during the schedule and you can ask for a break at any time you wish. We will also offer you tea and coffee as refreshment during the schedule. You are free to take regular breaks from testing whenever you wish to do so.

We may also ask you whether you would like to take part in one or more sub-studies that we are carrying out. These will involve more detailed brain scanning a lumbar puncture or an MEG scan. We may also ask you if you would like to participate in another study (Cognitron) organised by Imperial College. If you are interested to participate in the Cognitron study we will send your email address to the study team at Imperial College. They will send you a link to the study website. The results from your participation in the Cognitron study will be shared with UCL.

Will I receive any payment for participating in this study?

We will refund any travel or other reasonable expenses you incur in order to attend the research visits.

What will happen to the results of the study?

Results of the study will be available at a group level once the study is completed. We then plan to publish the results of the study in scientific journals. Information that would identify you or any other participant will not be included in any publication. It will not be possible for you to know your own test results.

Will I find out the results of my genetic tests?

No. The tests in this study are performed on a research basis and cannot be used for clinical purposes. In some circumstances the research tests may indicate that future NHS based genetic or chemical testing may be useful in accurately diagnosing the disease you have and in determining the risk of disease to other members of your family. We will ask you to indicate whether you would wish to be informed about this, in advance. If you do choose to be informed of future test developments we will arrange for you to be given appropriate genetic advice at that time. This will be via an NHS genetics service and will be discussed with you by your doctor, a member of the research team who arranged the original research blood sample, or by Dr Weil. Currently these types of tests do not lead to any new treatments or change in your current treatment, although this may change in the coming years.

What are the possible disadvantages and risks of taking part in the study?

The medical assessment and neuropsychological testing may involve you answering questions that are of a personal nature and the testing may be tiring. You do not need to answer any questions you do not wish to, and you may ask for a break during the testing if you need one.

Taking blood can result in minimal discomfort when the needle is inserted and there may be a small risk of bruising or a local skin reaction.

You may feel claustrophobic or uncomfortable lying in the MRI scanner. You will hear loud knocking noises but we will provide you with earplugs to wear during the MRI. You can ask to stop the MRI at any time if it becomes uncomfortable.

Eye drops can cause unwanted side effects in some people. They can cause mild stinging for a few seconds and sensitivity to light. This usually passes as the effects of the drops wear off. Some people find it helpful to wear dark glasses for a short while, so you may find it helpful to bring sunglasses with you. The eye drops can also cause blurred vision for one to two hours. **You should not drive or use machines until your vision is clear again.** Some people also develop headaches or feel sick with the drops. This usually passes within a few hours soon. If you and your spouse or partner are being tested on the same day, we will ensure that we do not administer eye drops to both of you on the same visit.

Rarely, people can be allergic to eye drops. If you notice a rash around your eyes or swelling or itching, please speak with the study team or to your GP.

During the eye examination and the retinal scan we will ask you to remain as still as possible, so that we can get a good view of your eyes. In addition, the eye examination involves a bright light shining into your eyes for a short period of time. Some people find this mildly uncomfortable.

What are the possible benefits of taking part in the study?

Participation in this study will not benefit you personally. However, we hope to gain new insights into the diagnosis and progress of Parkinson's disease and cognitive impairment associated with Parkinson's disease and hopefully this will contribute to helping others in the future.

How will personal information about me and my involvement in the study be kept confidential?

Any information collected during the study will be kept confidential. Assessment and test results will be stored on a secure, confidential, computer network on the University College London (UCL) system, accessible only to members of the study. Study data are also stored on a secure online data repository hosted by https://aimes.uk/. The Chief Investigator has full control over access to data held on the Aimes system. The Chief Investigator will give members of the research team access to the data and they may also provide access to study collaborators e.g. IT professionals in order for

them to provide technical support. Collaborators will be given access to the data in accordance with a data access agreement with UCL.

Blood and/or CSF samples may be sent to external laboratories for specialist analysis. Your samples will be labelled with a study identifier and will not include any personal identifiable information. The external laboratories will be required to enter into a legal agreement with University College London. We will ask for your consent to share any new or previously donated samples.

Gait video analysis information will be made available to a partner organisation Machine Medicine Technologies Ltd. They have signed an agreement confirming that they will hold the data securely and will not share this information with third parties. When this study is completed we would like to continue to hold the data on the computer network and any blood samples as it may be helpful to look again at the data and samples in the light of discoveries that may be made in the future. We will protect your personal information in accordance with UCLH NHS Trust Information Governance policy; the handling, processing, storage and destruction of data will be conducted in accordance with current UK data protection legislation and with the General Data Protection Regulations to ensure that confidential information is safeguarded.

If you choose not to remain in the study or it is decided that you should not continue in the study, data and samples already collected will be retained and included in the analysis of results from the study.

What if I develop cognitive problems during the study, will I still need to take part?
You can withdraw from the study at any point. If you develop cognitive problems, you can still take part as long as you are able to understand the purpose and the nature of the research, what the research involves and are capable of retaining the information in order to decide that you would like to be involved.

Involvement of your general practitioner and hospital clinician
With your consent we will inform your General Practitioner (GP) and main hospital clinician of your involvement in the study. Your GP and hospital clinician will not routinely receive any information or results from your assessments or investigations, but we will advise them of any information relevant to your health. For example, if the MRI scan or eye tests show something that requires medical attention, the study team will let you know and will inform your GP and hospital clinician. We will also ask for your consent to contact your GP in the future should we lose contact with you.

You should be aware that being in a research study does not take the place of routine physical examinations or other appointments with your doctor and should not be relied upon to diagnose or treat medical problems.

Who is organising and funding this research?

This study is organised by the Institute of Neurology, a research department linked to UCL and UCLH NHS Foundation Trust. The study is funded by a research grant awarded to the Chief Investigator by UCL and the Wellcome Trust. The study is sponsored by University College London (UCL).

What if there is a problem?

If you or your relatives have any concerns about the research study you can speak to a member of the research team who will do their best to answer any questions. Contact details are at the end of this information sheet.

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this. You, your relatives or your informant can also contact the UCLH Patient Advice and Liaison Service at the following address; PALS, Box 25, National Hospital for Neurology and Neurosurgery, Queen Square,
London WC1N 3BG

In the unlikely event that you are harmed by taking part in this study, compensation may be available. If you suspect that the harm is the result of the Sponsor's (University College London) or the hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Dr Rimona Weil who is the Chief Investigator for the research and is based at the Institute of Neurology, Queen Square, London WC1N 3BG. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Who has reviewed the study?

This research project has been reviewed by the Research Ethics Committee, and has been subject to comprehensive review as part of a competitive funding application process.

Further information and contact details

If you would like any further information or have any questions about this research study please contact
Dr Rimona Weil, Clinician Scientist: 07984462180 or 0203 448 3048

Assistant Researcher: Naomi Hannaway: 07821833024
The Institute of Neurology
The National Hospital for Neurology and Neurosurgery
Queen Square
London, WC1N 3BG

Research at UCL and your data

UCL is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records 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. UCL will keep identifiable information about you for 20 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 information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible. You can find out more about how we use your information by contacting data-protection@ucl.ac.uk or Data Protection Officer, UCL Gower Street, London WC1E 6BT. Further information is provided in UCL's health and care research privacy notice: https://www.ucl.ac.uk/legal-services/privacy/participants-health-and-care-research-privacy-notice. The lawful basis that will be used to process your personal data is: 'Public task' for personal data and 'Research purposes' for special category data

The Institute of Neurology (IoN; the study site) will collect information from you and from your medical records for this research study in accordance with our instructions and the study protocol. The IoN will keep identifiable information about you for 20 years after the study has finished.

The IoN will use your name, address, date of birth and hospital number to contact you about the study and to make sure that relevant information is recorded for this study. Individuals from UCL (the sponsor) and other regulatory organisations may look at your health and research records in order to oversee the accuracy and quality of the research. The IoN will pass these details including any information collected from your health records to UCL. The only people at UCL who will have access to this information will be those individuals who may need to contact you for regulatory purposes e.g. to talk to you about a concern, complaint or unexpected or adverse event related to the research study or audit the data collection process.

UCL will collect information about you from your health records and other databases for this research study. This information may include your name, address, date of birth, hospital number. It may also include health information, which is regarded as a special category data of information in the General Data Protection Regulation. This information will be used to verify and interpret the results of the research tests.

When you agree to take part in a research study, the information about your health and care may be provided to researchers organising other studies in this organisation and in other organisations; these may be other universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

Your information could be used for research in any aspect of health care and could be combined with information about you from other sources held by the researchers, the NHS or Government. Where this

information could identify you, the information will be held securely with strict arrangements about who can access the information. The information would only be used for the purposes of health and care research or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance. Where there is a risk that you can be identified, your data will only be used in research that has been independently reviewed by an ethics committee.