## PARTICIPANT INFORMATION SHEET

MANIFEST GENETIC PD CARRIERS

**Study title**

**Molecular and functional imaging of Parkinson’s pathology in SNCA, Parkin and PINK1 mutation carriers.**

**Short title: Molecular and functional imaging in Monogenic PD**

**Chief Investigator:** Professor Marios Politis MD MSc DIC PhD FRCP FEAN; University of Exeter, London, United Kingdom

**Funder:** Michael J Fox Foundation for Parkinson’s Research

**Invitation**

You are invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take your time to read the following information carefully and discuss it with others if you wish. If anything is unclear or if you would like more information please get in touch with one of the study team. It is important that you take the time to decide whether or not you wish to take part.

Thank you for reading this.

**What is the purpose of the study?**

The purpose of this study is to find a biomarker for a disease called Parkinson’s disease (PD). A biomarker is an indicator of the presence of a disease, that can be measured, and that is able to give information about the progression, or severity, of it. PD is a chronic neurological disease that progresses over time and causes a variety of symptoms, such as slowness of movement, stiffness and shaking. The symptoms of PD are caused by the malfunction and death of vital nerve cells in the brain. We do not know what causes PD and we do not have a biomarker for it. Generally, PD occurs without a known cause, and is called sporadic PD. In a few cases, however, PD occurs because of a genetic mutation, and it is called genetic PD. Patients with genetic PD share features to sporadic PD patients. It is believed that studying people who carry mutations for genetic PD mutations would provide precious information on what are the causes of PD and help to devise successful treatments.

In this study, we aim to find a biomarker of PD. To do so, we will use imaging scans called Positron Emission tomography (PET), Single Photon Emission Computed Tomography (SPECT), and Magnetic Resonance Imaging (MRI). The PET and SPECT scans use small amounts of radiation and specific compounds called tracers, to study chemical changes in the brain in a way not possible with any other procedure. The MRI uses magnetic fields to generate images of brain structure and function.

We will also use a blood and urine collection and a special collection of cerebrospinal fluid, a liquid that bathes and protects the brain, with a procedure called lumbar puncture. This last procedure is optional and suitable candidates can participate in our study even if they don’t want to undertake this procedure.

Our findings will provide a deeper understanding of the brain changes in PD. More importantly, this study will help with the discovery and development of new medications aiming to delay progression of PD symptoms.

**Why have I been invited?**

You have been asked to participate because you are a confirmed carrier of a mutation for genetic PD and you have symptoms of PD.

**Do I have to take part?**

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you have agreed to take part, you are still free to withdraw at any time without giving any reasons and this will not affect the standard of hospital care you receive.

**What is involved in this study if I take part?**

If you are suitable, and agree to undergo this study, we will arrange the schedule of visits for this study with you.

The study will take place in London, in three research sites that are located near to each other. The NIHR Imperial Clinical Research Facility (CRF) at Hammersmith Hospital in London, for clinical assessment, Invicro London for PET and MRI imaging assessments, and Imperial Healthcare Nuclear Medicine Department for the SPECT scan. Both Hammersmith Hospital and Invicro are located at Hammersmith Hospital Campus (Du Cane Road, W12 0NN, London), and have established expertise in cutting-edge clinical research. Both the NIHR Imperial CRF and Invicro provide a pleasant environment for the patients and world-class capabilities by bringing together state-of-art equipment and research methodology. In the present study, the role of Invicro is that of a research facility with no commercial interest.

We will provide and arrange for you all transportation to and from London and the research sites for you and one companion, if necessary.

There is no strict schedule of the study visits. We will schedule the study visits with you and will do our best to arrange the visits at a time which is convenient for you and depending on the availability of the facilities. After the first study visit (Visit 1), we may change the order of the other visits if it is necessary. We will try to arrange visits on consecutive days or with some days apart depending on your preferences, and the availability of the facilities. In case we will arrange visits on consecutive days, if you would like, we can provide accommodation for you and one companion in an accommodation facility located in Holborn House, in Du Cane Road, between Hammersmith Hospital and Invicro, in West London.

Throughout the visits, we will provide refreshments. As a small thank you for the time taken to participate to this research, we will offer you £200 after completion of the study.

Please see below a map of where we are in West London and where exactly Hammersmith Hospital and Invicro, where you will attend for the study visits, are located, as well as a table that summarizes the schedule of the visits.

Map

Description automatically generated

**Summary of Visits**

|  |  |  |  |
| --- | --- | --- | --- |
| **Visit 1** | **Visit 2** | **Visit 3** | **Visit 4 (optional)** |
|  |  |  |  |
| -Signing of the informed consent form  - Screening and clinical assessment (about 3 hours)  - Vital signs1  -Blood & urine sample (about 15 minutes)  -Urine pregnancy test  (approx. 6 hours for the visit, including 1 hour of breaks) | -Urine pregnancy test  -Body weight  -Vital signs pre & post PET scan1  -Intravenous cannulation  -One CT scan  -[11C]DASB PET scan (about 1.5 hours)  -MRI scan (about 1.5 hours) | -Urine pregnancy test  -Vital signs pre & post SPECT scan1  -Intravenous cannulation  -[123I]FP-CIT SPECT scan (up to 45 minutes for the scan, up to 4 hours for the whole procedure) | -Vital signs pre & post lumbar puncture1  -Lumbar puncture for CSF assessment (about 2 hours for the procedure and for the monitoring) |

1Measurement of blood pressure, heart rate, and temperature.

**Visit 1:**

Screening and clinical assessments will last up to 3 hours and will take place at the NIHR Imperial Clinical Research Facility at Hammersmith Hospital. During this time, you will have the opportunity to discuss the study with the doctor, ask any questions you may have and then, if you agree to take part into this study, you will be asked to sign the consent form, a copy of which will be given to you for your records. No research related activity can take place until you have given your informed consent. If you decide to perform the Visit 4, that is optional, we will ask you to sign the Informed Consent tab for the Visit 4.

If you are taking any medication for Parkinson’s disease, we will ask you to withdraw the medications from the evening before. During the visit, you may feel that the usual symptoms of Parkinson’s disease (tremor, rigidity, slowness of movement), may reappear. You will be allowed to retake your medications soon after the clinical visit (see below).

At this visit we will collect the following information to make sure you qualify to be part of the study:

* A review of your medical history, and of family history for PD.
* A physical exam, including blood pressure, pulse, temperature, weight, height and body mass index.
* A neurological examination in order to assess your clinical status.
* Review of any medications you are currently taking.
* Short questionnaires and scales to check the motor symptoms (2 tests altogether). If you are taking Parkinson’s Disease treatment (levodopa or dopamine agonists), we will ask you not to take your medication in the morning of this visit day. After performing these scales, you will be asked to take your medication as usual, and the same examination will be repeated after approximately 1 hour.
* Short questionnaires to measure your thinking and memory, and quality of life (32 tests altogether)
* Computer tests to check the level of memory, attention, reasoning, etc (8 tests altogether)
* A blood sample will be taken to assess any bleeding disorders and part of this will be sent to Edinburgh Genetics to measure biomarkers of the disease. The amount of blood withdrawn will not exceed 45ml. (We will ask you to fast 8 hours prior to the blood sampling. If this is not possible, a low-lipid meal should be consumed according to our instructions.)
* A urine sample will be collected (about 10ml) to measure biomarkers and perform urine pregnancy test for female of childbearing potential.
* A questionnaire to check whether it is safe for you to have an MRI scan.
* This visit will last approximately 6 hours (including 1 hour of breaks).

**Visit 2:**

This visit will take place at Invicro. During this study visit, the following information will be collected:

* Information about your health and medications you are taking.
* Your blood pressure, pulse, temperature, weight and body mass index will be taken.
* If you are a female of childbearing potential, a urine sample will be collected (about 10ml) to test for pregnancy.
* A brain scan using positron emission tomography (PET) will be performed. You will be asked to lie on your back on a bed with your head resting in the scanner. Before each scan, one needle will need to be placed into a vein to administer the tracer. The tracer injection should not cause any significant discomfort. During the PET scan you will also be asked to undertake up to two low dose brain CT scans, which are necessary to measure data from the PET scan. If you are under Parkinson’s Disease treatment (levodopa or dopamine agonists), we will ask you not to take your medication in the morning of this visit until the completion of this scan. After this scan will have finished, you can take your medications normally.
* A brain scan using magnetic resonance imaging (MRI) will be performed. You will be asked to lie on a bed that can slide so that your head is moved into the scanner. A special head coil (like a helmet), that enables the scanner to obtain the brain images, will be placed on your head before the bed slides into the scanner. Having an MRI scan will not require you to have any injections. During the MRI scan, you can expect to hear the MRI scanner make some loud thumping sounds. You will be offered earplugs to reduce the sound for your comfort. This scan usually lasts about 1.5 hours (but may take a little longer, if you need time to settle in comfortably).

This visit will last approximately 6 hours. If you experience any distress during the scans, we will endeavour to provide you with any support you may require.

If there is a problem with the production of the PET tracer or under special circumstances, you may be asked to attend an additional visit at Invicro.

If you have previously had any [123I]FP-CIT SPECT scan(s) (also known as a DAT scan), we will ask if you are happy for us to retrieve a copy of the imaging data to be used for the study analysis. In this case you might not need to do additional [123I]FP-CIT SPECT scan(s).

**Visit 3:**

You will be asked to attend the Imperial Healthcare Nuclear Medicine Department and the following information will be collected:

* Information about your health and medications you are taking.
* Your blood pressure, pulse, temperature, weight and body mass index will be taken.
* If you are a female of childbearing potential, a urine sample will be collected (about 10ml) to test for pregnancy.
* A brain scan using single-photon emission computerized technology (SPECT) This scan is a type of nuclear imaging test, which means it uses a radioactive substance and special camera to create 3-D pictures. During this time, you will be asked to lie on your back on a bed with your head resting in the scanner. Before each scan, one needle will need to be placed into a vein to administer the tracer. The day of the SPECT scan we will ask you to take iodine tablets to protect your thyroid from absorbing the iodine contained in the SPECT scan tracer. These iodine tablets will be given to you the day of Visit 1. If you are under Parkinson’s Disease treatment (levodopa or dopamine agonists), we will ask you not to take your medication in the morning of this visit until the completion of this scan. After this scan will have finished, you can take your medications normally.

This visit will last about 4 hours.

**Visit 4 (optional):**

This visit is optional. You will be asked to return to the NIHR Imperial Clinical Research Facility at Hammersmith Hospital. During this visit you will undergo the following procedures:

* Information about your health and medications you are taking.
* Your blood pressure, pulse, temperature, weight and body mass index will be taken.
* Lumbar puncture to collect cerebral spinal fluid for storage and research tests. Approximately 15-20ml of cerebrospinal fluid (CSF) will be collected from the base of the spine. The collection will take about 30 minutes. If you are under Parkinson’s Disease treatment (levodopa or dopamine agonists), we will ask you not to take your medication in the morning of this visit until the completion of this procedure. After this procedure will have finished, you can take your medications normally.

You will stay in the ward of the NIHR Imperial Clinical Research Facility for about two hours to make sure that there is no side effect from the procedure (e.g. headache, see below) and then you will be able to go home. You will be re-contacted by phone 7 to 10 days following the procedure to ask you how you are doing and ask questions about your health.

**Reimbursement for Participation**

As a little thank you for your participation, you will be paid £200 for completion of the study. We will reimburse transportation to and from home to the hospital and refreshments throughout your visits. Taxis will be made available for all visits. If it is needed, we will provide you accommodation for you and one companion at no cost.

**Restrictions:**

You will be asked to fast from the evening before the Visit 1 until after your blood sample has been collected for clinical laboratory assessments. Before your PET and SPECT imaging scans, you will be asked to avoid drinking alcohol for at least 72 hours before your PET and SPECT imaging visit until you receive your post-assessment phone call. You will also be asked to refrain from taking any drink with caffeine for 12 hours before the PET and SPECT scan. You will also be asked to discontinue smoking or using any nicotine-containing products on the day of the PET and SPECT scan until the end of the PET and SPECT imaging visit and lastly, you will be asked to discontinue the use of melatonin for at least 24 hours before your PET and SPECT imaging visit until the end of the PET and SPECT imaging visit. There are some medications that may interfere with the results of the PET and SPECT scans. These medications are usually taken for various conditions, such as to improve the mood, to increase the level of attention, or to tackle the pain. The investigator will check whether you are taking any of these medications and will instruct you on whether and how to refrain from taking these medications up to three days before the PET scans. If the investigator decides that it is risky to stop these medications even for three days, then unfortunately you cannot participate to this study. You must follow highly effective birth control measures throughout this study.

**Incidental findings:**

You should be aware that the scans used in this study might identify a previously undiagnosed illness or detect something which is abnormal and potentially clinically significant (known as an ‘incidental finding’). In the unlikely event of this happening, we would inform you as soon as possible and discuss the implications and options available.

With your consent we may refer you back to your GP or another clinician for follow-up if appropriate. As a result of incidental findings you might need to be withdrawn from the research study, but we would discuss this with you.

If a possible malignancy (cancer) is detected, your images will be reviewed by a multi-disciplinary team of experts from Imperial College Healthcare NHS Trust who will attempt to make a diagnosis and recommend a plan for treatment. This is done automatically to ensure that it is dealt with urgently, and may happen before we have been able to contact you.

It is important to us that you are fully informed so that you can make decisions for yourself about taking part in research at the ICRF. We will do our best to communicate with you openly and clearly, so please ask questions at any time if there is anything that you’re unsure about.

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

**Placement of venous cannula:** Insertion of a cannula (a small plastic tube) into a vein may cause brief discomfort as the cannula penetrates the skin, which is similar to the discomfort you may feel when having an injection. Sometimes people can feel lightheaded or even faint after having blood drawn. Risks of cannulation include minor local bleeding and bruising. Very rarely, a blood clot could form around the cannula. Most people have no after-effects of cannulation. However, occasionally, a scar may occur, though when this happens, the scar left over the long term is usually small. More rarely, there can be some discomfort lingering after the cannula insertion.

**Lumbar puncture (optional):** The most common risks of lumbar puncture are local pain at the site and a temporary headache. A local anaesthetic is injected to make the area go numb during the procedure. This stings for a couple of minutes and then the skin goes numb. There is a small risk of an allergic reaction to the local anaesthetic. You will be monitored by a study doctor throughout the procedure. After the procedure, you will need to lie down for an hour. About 10% of people get a headache after a lumbar puncture. Usually this gets better with water and mild painkillers, but occasionally it is severe. Rarely, a second procedure similar to a lumbar puncture is needed to treat the headache. There is a slight risk of infection because the needle breaks the skin surface, providing a possible entry point for bacteria. To reduce the risk of infection all lumbar punctures will be performed by experienced personnel in a sterile environment, as per common practice. There is a small risk of bleeding in the spinal canal, though to avoid this risk, prior to the procedure, a blood test will be conducted to screen for blood clotting disorders. There is a rare chance that the collection of CSF may decrease significantly the pressure of this liquid in the brain, and cause the shifting of brain tissue resulting in a compression of the brain. This is a serious side effect that only occurs if there are concomitant problems in the brain such as an abscess or a tumor. To rule out this complication, we won’t enrol anyone who has previously obtained an MRI scan with evidence of a clinically significant neurological alteration. A very rare possible complication is that of a spinal cord damage or paralysis because of the insertion of the needle. This complication is ruled out by inserting the needle well below (at least 2-3 cm) where your spinal cord ends.

**PET and SPECT scan:** During the PET scan, you may experience discomfort associated with having to lie still with your head in an enclosed space for a long period of time. The space for the head is narrow and for some people this can be a source of discomfort. Some people may even feel claustrophobic, that is, have a fear of confined spaces. During the PET scans, the door of the scanner room will always be open and an operator and a physician are always present there or in the room immediately nearby, and in communication with you. You can speak with them all the time in case of any problem. To make you feel as relaxed as possible, some background music can be played in the room.

**MRI scan:** It is not safe for people with some implants, for e.g. pacemakers, stents, aneurysm clips etc. in the body to undergo MRI. In addition, losse metallic devices like hearing aids can become detached or stop working. The metal can be pulled away from the body and towards the big magnet in the MRI scanner, which could cause injuries. It is thus very important to notify the study doctor during the screening visit, if you have any implants in your body. The top part of your body and your head will lie inside the scanner, which is a confined space and make some people feel anxious. Please notify the study doctor if you suffer from claustrophobia. During the MRI scans, the operator and the physician are not allowed to stay in the scanner room for safety reasons, however they will be in a room next to the scanner room. You will have a microphone to speak with them in case you need anything. You will also have a button to press to attract the attention of the operator. During the scan, you will hear loud thumping/pulsating noises while the scanner is running which can be disturbing or stressful for some people. We will provide you with ear plugs. During the Screening Visit, we will conduct a questionnaire to check whether it is safe for you to have an MRI scan. This check will be repeated on the day of the MRI scan. During the MRI scan, some of the MRI sequences used are classified as research sequences. These research sequences are called diffusion imaging, functional imaging and arterial spin labelling. The research sequences have been provided by a 3rd party. This means that the MRI scanner will be used in a different way to what is standard by the manufacture (we call it “off-label”). Using these sequences helps to reduces the scan time and provides better quality image data for the research study.

You will be asked to change into hospital scrubs before your scan. You will not be able to take anything into the scanner with you, but a locker will be provided for your valuables.

**Risks associated with administration of PET and SPECT tracers and with ionizing radiation exposure:** The PET and SPECT tracers used in this study will be injected at a dose of less than 10 micrograms at each scan. They have been demonstrated to be safe at doses up to 1,000 times higher than the doses used for this study.

If you take part in this study you will have PET and SPECT scans. This will be extra to those that you would have if you did not take part in the trial.

These procedures use ionising radiation to form images of your body. Ionising radiation may cause cancer many years or decades after the exposure. We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime.

Taking part in this study will increase the chances of this happening by an additional 0.04%. In order to keep your radiation exposure to a minimum we will ask you about procedures involving radiation that you have undertaken over the past three years, for example x-rays, CT scans, PET scans and others.

**Reproductive risks:** Along with other procedures involving radiation (including x-rays), PET scans can be hazardous to an unborn child. If you are a woman of childbearing age you should not take part in this study unless you are on a reliable form of contraception, and even if this is the case a urine pregnancy test prior to the PET scans will be performed. It is essential that, if you are a woman of child bearing potential (that is, pre-menopausal and non-sterilized), or if you are a man that is non-vasectomized, you must agree to use one or more acceptable, highly effective forms of birth control throughout your participation in this study. If you have any questions regarding reliable, highly effective birth control, please ask the study site staff to provide you with this information. If you are a woman and become pregnant while taking part in this study or you are a man and your female partner becomes pregnant you must inform the study doctor immediately.

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

You will not receive treatment nor receive any direct benefits from participation. However, the knowledge acquired from this study will improve our understanding of Parkinson’s disease and may help us to provide the means for the development of better drugs for this disease. As there are no alternative methods to study the brain of a living person in real time, we believe that the added risk in this study due to the additional radiation exposure is justified.

**What are the alternatives to participating in this study?**

The research study is for research purposes only. The only alternative is to not participate in this study.

**What are the costs to participating in this study?**

There will be no cost to you to participate in this study.

**What if something goes wrong?**

The University of Exeter has insurance cover in place to cover its legal liability for injury or illness arising from this study. If you are following a private insurance scheme, you should notify your insurer that you are taking part in this study. If you are harmed due to someone’s negligence, then you may have grounds for a legal action. In case you are harmed due to negligence during or as consequence of procedures carried out by NHS staff, for example because of blood sample collection, NHS indemnity scheme will apply.

If anything goes wrong, or if you have a concern, you may wish to make a complaint. The Patient Advice and Liaison Service (PALS) can support you throughout the complaint process. To find out more, please visit the PALS website https://www.rdehospital.nhs.uk/patients-visitors/patient-advice-liaison-service-pals/ or contact PALS at Royal Devon & Exeter NHS Foundation Trust by telephone on 01392 402093 or by email on rde-tr.PALS@nhs.net / dre-tr.complaints@nhs.net. The Imperial College Healthcare Trust PALS contacts are: Telephone: 020 3313 3322 Email: imperial.PALS@nhs.net Postal Address: PALS manager, Hammersmith Hospital, Du Cane Road London W12 0HS.

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

The University of Exeter is sponsor for this study based in the United Kingdom. We will be using information from you and 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.

In 2018 regulatory changes in the way that data is processed came into force, with the EU General Data Protection Regulation 2018 (GDPR) and the Data Protection Act 2018 (DPA 2018). Since the UK left the EU, the key principles of EU GDPR have been adopted in the UK GDPR (a ‘UK-only’ version) and the DPA 2018 still applies.

The University of Exeter terms its lawful basis to process personal data for the purposes of carrying out research as being in the ‘public interest’. The University continues to be transparent about its processing of your personal data and the participant information sheet should provide a clear explanation of how your data will be collected, processed, stored and destroyed. If you have any queries about the University’s processing of your personal data that cannot be resolved by the research team, further information can be obtained from the University of Exeter’s Data Protection Officer via the link; https://www.exeter.ac.uk/aboutoursite/dataprotection/dpo/

If you have any concerns about how your data is controlled and managed for this study, then please contact the Sponsor Representative: Anthony Walsh (details at the end of this information sheet.)

The University of Exeter will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad, including:

- The Clinical Trials Coordination Centre (CTCC) at the University of Rochester (representatives who maintain, manage, and monitor the information collected in the study);

- The Informatics Core at the Laboratory of Neuro Imaging (LONI), Los Angeles, CA (representatives who maintain, manage, and monitor the central data repository);

- The PPMI Core at the Institute of Neurodegenerative Disorders and Molecular NeuroImaging, LLC (representatives who maintain and manage the data);

- Genetics Coordinating Core at Indiana University School of Medicine (representatives who maintain, manage, and monitor the clinical data collected in the study);

- The Michael J. Fox Foundation for Parkinson’s Research (MJFF), the funder of the study;

- The Institutional Review Boards/Ethics Committees at the University of Rochester, in the United States and London Bridge Research Ethics Committee (committees that review research as required by regulations to make certain your rights as a research participant are protected);

- Clinical research monitors (representatives who visit each study site to make sure the study is being conducted according to regulations);

- NIHR Imperial Clinical Research Facility which is part of Imperial College Healthcare NHS Trust;

- Invicro, a Konica Minolta Company;

- The University of Exeter, the sponsor of the study.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Your anonymized blood and/or CSF samples will be used for detection of biomarkers related to Parkinson’s disease. They will be shipped for analysis to third parties which are outside the University of Exeter. They will also be stored for future research in biorepository which are located at the University of Exeter and in other repositories which may be located in countries that may not have the same or as strict privacy laws as this country, including the United States. However, each recipient will be required to enter into an agreement under which the recipient will be required to comply with local laws applicable to their use of the information.

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.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Individuals from the University of Exeter regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people at the University of Exeter who will have access to information that identifies you will be people who need to contact you regarding the research study or to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

The NIHR Imperial Clinical Research Facility is part of Imperial College Healthcare NHS Trust, and we rely on several NHS systems and procedures to support our research. To include you in a study we need to record information in your medical healthcare record, whether you are a patient or a healthy volunteer.

Healthcare records may be in paper or electronic format and will typically include laboratory test results, radiological imaging (e.g. ultrasound scans, X-rays, MRI etc), clinical notes, routine observations, prescription charts (a list of medicines given to you) and other study-specific information which is collected as part of the research. Such information may be valuable to support your normal health care now, or in the future. If you are not already a Trust patient, we will need to register you.

Although information collected as part of this study will be available in your medical records, a duty of confidentiality applies, and staff within the NHS may only access your records if they have a legitimate and lawful reason to do so. If you have any concerns about this, please speak with your study doctor.

All information collected in this study will be kept strictly confidential and stored either on an encrypted password protected computer, or in a locked cabinet in a secure office at the University of Exeter, which can only be accessed by the research team. You will be allocated a unique participant number, to ensure your information will be protected and cannot be identified outside of the research team. Any personally identifiable information will be stored separately and securely from information obtained from the research, it will only be kept for 10 years after the study has finished and securely destroyed at the end of the 10 years.

Your rights to access, to 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.

The University of Exeter will keep identifiable information about you from this study for 10 years after the study has finished. We will use this information for research purposes only.

Referral forms containing name, date of birth and address will be sent to Invicro London through an encrypted process in order to correctly identify you prior to your scans.

If you consent to take part in the research, with your permission we will write to your GP to inform him/her that you are participating in this study.

If you consent to take part in the research, we will ask you the consent to be recontacted by researchers at the University of Exeter regarding future ethically approved research studies. This is optional and not agreeing to this will not affect the participation to this study in any way.

You can find out more about how we use your information by contacting the principal investigator Prof. Marios Politis ([m.politis@exeter.ac.uk](mailto:m.politis@exeter.ac.uk)) or the study team:

Study Doctor:

Dr Edoardo de Natale Tel: 07503 741242 Email: [e.de-natale@exeter.ac.uk](mailto:e.de-natale@exeter.ac.uk)

Study Coordinator:

Name: Martin Howard Tel: 01392 723 037 Email: [M.Howard3@exeter.ac.uk](mailto:M.Howard3@exeter.ac.uk)

All employees working in the NHS are bound by a legal duty of confidence to protect personal information and therefore any information you give during this study will be kept confidential. Should we be concerned about your health or wellbeing we may discuss this with your clinical care team/GP.

Data collected during your participation in this research project may also be stored electronically on a research PET database at the University of Exeter and Invicro London and may be used in the future by both Invicro London and the University of Exeter to compare with results from other studies. However, such data will be anonymised so that you cannot be identified on the database. All stored data will comply with the provisions of the General Data Protection Regulation (GDPR), and of the Data Protection Act 2018 and will only be accessible via written permission of the Chief investigator of this study. Your anonymised data may be used in future ethically approved research studies, we will ask for your consent for this. The information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

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

The results of the research are likely to be published in a peer-reviewed scientific journal. You will not be identified in any report/publication.

If you wish, feedback will be sent to you from the research doctor with the results, which will be in a manner understandable to a non-medical person.

**Who is organising and funding the research?**

This academic, non-commercial study is funded by the Michael J Fox Foundation for Parkinson’s Research, a large non-profit foundation based in the United States. University of Exeter is the sponsor of the study.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the London Bridge Research Ethic Committee. The study has also been reviewed and approved by the NHS Health Research Authority (HRA) and the Administration of Radioactive Substances Advisory Committee (ARSAC).

**Contact for Further Information**

If you have any questions or there is anything you wish to discuss please contact the principal investigator Prof. Marios Politis ([m.politis@exeter.ac.uk](mailto:m.politis@exeter.ac.uk)) or the study team:

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The study team is located at the London Offices, Exeter Medical School, Translation and Innovation Hub, Central Working 4th Floor, 80 Wood Lane, White City, London, W12 0BZ.

If you agree to participate in this study, please sign the consent form. You will be given a copy of the information sheet and a signed consent form to keep for your records.