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## PARTICIPANT INFORMATION SHEET

SNCA MUTATION CARRIERS

**Study title**

**Evaluation of Serotonergic Neurotransmission in Premotor and Motor**

**Parkinson’s disease.**

**Short title: Serotonin release in premotor and motor PD.**

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

**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 better understand the mechanisms underlying a disease called Parkinson’s disease (PD). This is achieved with the identification and the study of biomarkers. A biomarker is a measure that indicates the presence of an abnormal process, condition or disease, and its progression. 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. We know that a few forms of Parkinson’s disease are caused by genetic mutations. We think that if we understand better what are the mechanisms the lead to the disease in the people with the genetic form of PD, we could devise treatments that can work for both the genetic form and the forms of PD for which we don’t know the cause yet.

In this study, 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 scan uses magnetic fields to generate images of brain and does not involve any radiation.

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 carry a mutation in the SNCA gene.

**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 and Invicro London for clinical and MRI and PET assessments, and Imperial Healthcare Nuclear Medicine Department for the SPECT scan. Hammersmith Hospital and Invicro London are located at Hammersmith Campus (Du Cane Road, W12 0NN, London). The NIHR Imperial College Clinical Research Facility provides comfortable clinical accommodation for study participants covering both long-term in-house monitoring as well as day visits. It is equipped to cater for studies from across the range of medical disciplines. Invicro London is a clinical imaging centre with established expertise in state-of-the-art molecular imaging techniques. Invicro London provides a pleasant environment for the patients and world-class capabilities. The Imperial Nuclear Medicine Department is a specialized hospital Centre for imaging and is located in West London. All appointments will be on a weekday. 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 £475 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

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|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Visit 1** | **Visit 2** | **Visit 3** | **Visit 4** | **Visit 5** |
| **(About 4 hours)** | **(About 4 hours)** | **(About 6 hours)** | **(About 5 hours)** | **(About 3 hours)**  **(optional)** |
| * - Signing of the informed consent form * - Screening and clinical assessments (about 3 hours) - Physical examination * - Vital signs1 * - Blood & urine sample collection (about 15 minutes) * - Urine pregnancy test * - Clinical scales * CANTAB | * - Urine pregnancy test * - Body weight * - Vital signs pre & post PET scan1 * - Venous cannulation * -One CT scan * -One [11C]DASB PET scan (about 1.5 hours) * - One MRI scan (about 1.5 hours) | * - Urine pregnancy test * - Body weight * - Vital signs1 * - Intravenous cannulation * - Arterial cannulation * -One CT scan * -One [11C]Cimbi-36 PET scan (about 1.5 hours) * - Vital signs1 * - Dexamphetamine * - One CT scan * - Second [11C]Cimbi-36 PET scan (about 1.5 hours) * - Vital signs1 | * - Urine pregnancy test * - Body weight * - Vital signs pre & post SPECT scan1 * - Intravenous cannulation * - One SPECT scan ([123I]FP-CIT) up to 45 minutes for the scan, up to 4 hours for the whole procedure | * - Vital signs pre & post lumbar puncture1 * - Lumbar puncture (about 2 hours for the procedure and for the monitoring) |

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

This study entails up to five (5) visits. Here below you find a description of the visits.

**Visit 1: Screening and clinical assessment, blood and urine collection.**

Screening and clinical assessments will last approximately 3 hours and will take place at the NIHR Imperial Clinical Research Facility. We will arrange a taxi to take you to the hospital and to return home. This will happen for all visits. Before the study visit starts, you will have the opportunity to discuss the study with the doctor, ask any question 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 written informed consent. If you decide to perform the Visit 5, that is optional, we will ask you to sign the Informed Consent tab for the Visit 5.

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). We will then assess your suitability to take part in the study and we will conduct a specific neurological examination and a few questionnaires and computerized tests to assess the presence of symptoms related to how you move, think, and behave, as well as a check of your blood pressure, heart rate, and electrocardiogram (vital signs). 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 the motor scale (called MDS-UPDRS), you will be asked to take your medication as usual, and the same examination will be repeated after approximately 1 hour. We will ask you to perform some tests to check how is your memory, and how you think, on questionnaires and with a tablet called CANTAB. We will ask you to provide a blood sample. This sample will serve to check if there is any problem with bleeding, and will then be sent to Edinburgh Genetics to measure biomarkers of the disease, and to test the DNA for the presence of genetic mutations. Any unused sample from the DNA analysis will be returned to the university of Exeter for Biobanking and future research The amount of blood that will be taken will be of up to nine teaspoons. 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. We will also ask you to provide a urine sample for chemical analysis and pregnancy test (only if you are a woman of childbearing potential).

**Visit 2: PET and MRI scan visit.**

This visit will take place at Invicro London. In this visit you will undergo one PET scan with administration of the tracer [11C]DASB, which studies the serotonin system.

We will first check for any adverse event (AE) since the first visit, and make a check-up of your blood pressure, and heart rate. Then we will insert the venous cannula for the injection of the tracer. The PET scan will last about 90 minutes. During this time, you will be asked to lie on your back on a bed with your head resting in the scanner. One member of the staff will always be available to assist you in case you need anything. The MRI scan does not need any placement of cannulae. For this exam, you will be asked to lie back on a bed during the duration of the scan. The total duration of the scan is of about 90 minutes. One member of the staff will always be available in another room to assist you throughout the duration of the exam.

The tracer injection should not cause any discomfort and no side effects have been reported from human studies that have used the same tracer injected in the present study. Before the PET scan you will also undertake up to two low dose brain CT scans, which are necessary to measure data from the PET scan. The CT scan is performed immediately before the PET scan and will last about 2-3 minutes. Refreshments will be offered after the PET scan.

**Visit 3: [11C]CIMBI-PET scans**

This visit will take place at Invicro London. In this visit you will undergo two PET scans with a tracer called [11C]CIMBI-36. This tracer also studies the serotonin system, and is used to check the capacity of the cells of the brain that produce serotonin to produce this substance. This is achieved by a pharmacological stimulation with a medication called dexamphetamine. During this visit, first, we will check for any adverse event (AE) since the first visit, and make a check-up of your blood pressure, and heart rate. We will then perform a short and easy medical test called Allen’s test, which serves to understand the blood flow in the arteries of your arms. Then we will insert the venous cannula for the injection of the tracer. Another needle will be placed into an artery in your wrist. This cannula is needed to collect a small amount of blood during the PET scan (around 132 mL in total or 27 teaspoons – one teaspoon = 4.92 mL) to aid the analysis of the data. Each PET scan will take about 1.5 hours. During this time, you will be asked to lie on your back on a bed with your head resting in the scanner. One member of the staff will always be available to assist you in case you need anything. After the first PET scan, you will be given the medication dexamphetamine. After you have taken the medication, you can rest for about three hours. From time to time, we will check the blood pressure and the heart rate. After about three hours, you will repeat the PET scan with the same procedures. After the second scan has finished, we will remove the arterial and venous cannulae and check again the blood pressure and the heart rate (see below for a description of the potential side effects of dexamphetamine).

The tracer injection should not cause any discomfort and no side effects have been reported from human studies that have used the same tracer injected in the present study. Before the PET scan you will also undertake up to two low dose brain CT scans, which are necessary to measure data from the PET scan. The CT scan is performed immediately before the PET scan and will last about 2-3 minutes. Refreshments will be offered after the PET scan.

**Visit 4: DaTSCAN SPECT**

This visit will take place at the Imperial Healthcare Nuclear Medicine Department. You will have received from 2 tablets of iodine. These tablets are taken the day of the SPECT scan to protect our thyroid from the iodine which is contained in the tracer injected. During this visit, first, we will check for any adverse event (AE) since the first visit, and make a check-up of your blood pressure, and heart rate. Then, we will ask you to take the iodine tablets, for the same reason described earlier. Then we will insert the venous cannula for the injection of the tracer. The tracer is called [123I]FP-CIT and studies the dopamine terminals. Then, you can rest for about four hours. After this time, you will start the scan. The total duration of the scan is of about 45 minutes. One member of the staff will always be available in another room to assist you throughout the duration of the exam. The tracer injection should not cause any discomfort and no side effects have been reported from human studies that have used the same tracer injected in the present study. Refreshments will be offered after the SPECT scan. 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 5: Lumbar puncture (optional).**

This visit is optional. This visit will take place in the Imperial Clinical Research Facility. This visit will last about 1.5 hours, with some extra time for monitoring. We will collect cerebrospinal fluid (CSF) using a technique known as lumbar puncture. CSF samples will be used to measure biomarkers of the disease. Lumbar puncture is a common procedure in both the clinical and research setting. The lumbar puncture procedure is optional. If you decide not to undergo this procedure, you still are entitled to take part to the other procedures of this study.

Lumbar puncture, also known as a ‘spinal tap’, is a minor procedure where a needle is used to withdraw about CSF from the base of the spine. It takes about 15 minutes and is done under local anaesthetic which numbs the area. You will be asked to lie on your side and curl up as tightly as you can. After cleaning the skin of the lower back, local anaesthetic is injected to make the area go numb. This will sting for a couple of minutes, and then the skin will go numb. A needle is then used to collect 2 tablespoons (15-20 mL) of CSF. You will stay in the private ward of the Imperial Clinical Research Facility for about two hours after the procedure to check that there is no side effect and then you will be able to go home. You will be contacted by phone 7 to 10 days following the procedure to make sure you are feeling OK.

The PET tracers will be produced at Invicro London the day of the PET scan. If there is a problem with the production of the PET tracer, or other circumstances, you may be asked to attend an additional visit at Invicro London. MRI may be performed before the PET scan and the order of the PET scans may change, if needed.

The blood and CSF samples for the biomarker analysis will be shipped from the Imperial Clinical Research Facility to a sample storage for analysis and storage for future research related to Parkinson’s Disease. A small amount of the blood and CSF samples will also be stored at a biobank located at University of Exeter.

**Incidental findings:** During your participation in a study we might identify a previously undiagnosed illness or detect something which is abnormal and potentially clinically significant (known as an ‘incidental finding’).

Normally 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.

**Medication restrictions**: We will ask you about your current and previous medications as there are some medications that should not be taken before the PET scans, as they can affect the results. Medications or supplements with known action on serotonergic systems must be discontinued prior to imaging measurements as follows: (a) For Serotonergic PET: antidepressants (i.e. tricyclic or selective serotonin reuptake inhibitors etc.) at least 60 days prior to PET measurement. 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.

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

**Cannulation**

Insertion of a cannula into a vein or artery may cause brief discomfort as the cannula penetrates the skin, which is similar to the discomfort you may feel when having an injection.  To insert the cannula into your artery we will use a local anaesthetic to numb the area so you do not feel pain. Detailed instructions on insertion of the arterial line and the care of the site after removal of the arterial line can be found in the leaflet provided to you with this information sheet. Risks of any 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 even 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. The full list of potential complications is as follows:

Common complications:

·         Temporary artery spasm (20%)

·         Bruising (14%)

Less common complications:

·         Localised site infection (0.72%)

·         Bleeding (0.53%)

·         Generalised infection (0.13%)

·         Damage to the fingers due to inadequate blood supply (0.09%)

Rare complications:

·         Paralysis of median nerve (runs from the forearm into the palm of the hand) (<0.1%)

·         Air embolism (air bubble trapped in a blood vessel.  When an air bubble travels along an artery, it moves through a system of blood vessels that gradually become narrower.  At some point, the embolus will block a small artery and cut off the blood supply to a particular area of the body.) (<0.1%)

·         Carpal tunnel syndrome (median nerve becomes pressed or squeezed at the wrist causing pain, weakness, or numbness in the hand and wrist) (<0.1%)

Most arterial cannula insertions are done without any problems.  You may notice bruising around the area where the cannula was inserted, which should disappear after a week or two.  The place where the cannula was inserted will heal quickly within a few weeks, with any marks fading with time.

If any of the following occur within 72 hours after the cannula was removed, you MUST consult the Study Doctor immediately.

·         Intense or sharp thumb or palm pain

·         If anywhere on your hand, fingers or thumb appears pale and cold or

·         If anywhere on skin to the hand, fingers or thumb appears dark or blackened and cold

·         If you notice an unusual ‘lump or bump’ over where the cannula was inserted

·         If you develop a fever (raised temperature) and feel unwell

·         If you feel a sudden shortness of breath

·         The dressing becomes soaked with blood (If you experience heavy bleeding), apply firm pressure to the area with the dressing supplied for 5 minutes and attend Accident & Emergency for advice/ treatment.  Please also notify the Study Doctor.

**Dexamphetamine administration**

Dexamphetamine is a marketed compound commonly used as a treatment for attention deficit hyperactivity disorder (ADHD) as well as narcolepsy (a condition that causes extreme daytime sleepiness). A single dose of 0.5 mg/kg, that will be used in this study, is not expected to produce any serious adverse events. Well-known side effects that can occur after a single dose of dexamphetamine include insomnia, restlessness and irritability along with dry mouth, sweating, tachycardia (accelerated heart beat) and palpitations. Severe reactions, such as psychotic symptoms, are very rare. Should any side effects occur, they do not last long and spontaneously self-resolve with time. There may be effects on mood such as euphoria, increased alertness, irritability, or anxiety, however, in previous studies conducted at Invicro, this dose of dexamphetamine did not induce such effects so we do not expect you to have any of these symptoms from dexamphetamine. In the unlikely event of any such effects, you will not be allowed to leave until any changes have resolved and you feel well. Treatment will consist in continuous observation of clinical conditions. Should adverse effects result in persistent or severe clinical conditions, you will be admitted to hospital until it is safe for you to go home.

**Lumbar puncture / CSF collection**

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. 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’s 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 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 enroll 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.

**Imaging procedures**

If you take part in this study you will have PET and SPECT scans. These 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 0.06%.

The MRI scan does not expose you to ionizing radiation, but it can be noisy (we will provide you with earplugs to counter this). An MRI is a very strong magnet, so if you think you may have any metal in your body (e.g. as a result of surgery, or an accident, such as metal filings in your eye due to welding accidents) you must let us know, so we can assess if the procedure will pose any risk to you. You should also let the study doctor know if you have any other implants in your body. There is otherwise no discomfort associated with MRI scanning, other than having to lie on your back and try to remain as motionless as you can for about 90 minutes. However, if you are claustrophobic you may find MRI difficult to tolerate, if so please let us know in advance. 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 MRI scan and you will not be able to take anything into the scanner room with you. A locker will be provided for your valuables.

You should be aware that the scans used in this study might reveal an unexpected fact about you that may have relevance for your health. In the unlikely event of this happening, we will discuss this with you and, if necessary, provide any support that you may require, such as arranging follow-up tests and/or treatment and informing your GP.

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

PET and SPECT scans are not a form of treatment and do not provide any direct benefits to participants. 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 *in vivo* the brain we believe that the added risk in this study due to the additional radiation exposure is justified.

**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 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.

Exeter University Research Ethics and Governance office contacts Telephone 01392 723 588 or email P.R.Baxter2@exeter.ac.uk . Postal Address Research Ethics and Governance Office, Lafrowda House, St Germans Road, Exeter, Devon, EX4 6TL

**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: Dr Antony Walsh (Contact details at the end of the 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) or the study team:

Study Doctor:

Dr E de Natale 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

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 and will only be accessible via written permission of the principal investigator of this study. Your anonymised data may be used in future ethically approved research studies. 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.

**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?**

The study is funded by the Michael J. Fox Foundation for Parkinson’s disease Research. The 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 Ethics Committee.

**Contact for Further Information**

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

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Study Coordinator:

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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.