Thank you for your interest in our research study.
Below is the participant information sheet which contains a full description about the questionnaires and tests involved. Please contact Elio Arruzza (Elio.Arruzza@unisa.edu.au or 83021241) if you would like to participate.

University of South Australia

Participant Information Sheet

Title	Relationship between an imaging marker of Parkinson's disease and body function
Short Title	Substantia nigra and body function
Project Number	*206838*
Project Sponsor	University of South Australia
Chief Investigator/ Supervisor	Associate Professor Gabrielle Todd
Associate Investigator(s)	Mr Elio Arruzza (UniSA) Mr Minh (Shayne) Chau (Charles Sturt University) Ms Thi (Haley) Vu (UniSA) A/Prof Robert Wilcox (Neurology SA) A/Prof Marc Agzarian (South Australia Medical Imaging) Professor Adam Vogel (University of Melbourne)

Introduction – What does my participation involve?

You are invited to take part in this research project if you are a healthy adult aged 18-80 years. This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want to take part in the research. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether to take part, you might want to talk about it with a relative, friend or local doctor. Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the tests and research that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

What is the purpose of this research?

Parkinson's disease (PD) is a neurological disease that causes characteristic problems with movement, in addition to abnormalities in a wide range of other body functions. The symptoms of Parkinson's disease result from a slow progressive loss of brain cells (neurons) in a part of the brain called the substantia nigra. This brain region is involved in movement, emotion, and cognition. Parkinson's disease is also associated with a diverse range of changes in other parts of the nervous system, that contribute to observed disturbances in other body functions. Examples of disturbed functions include reduced olfaction (sense of smell), constipation, sleep, blood pressure changes, and symptoms of depression. The substantia nigra can be viewed in a safe and non-invasive manner with transcranial ultrasound. In up to 90% of people living with Parkinson's disease, the area of bright signal (echogenicity) in the

substantia nigra is abnormally large. This observation has resulted in transcranial ultrasound of the substantia nigra being used to help diagnose Parkinson's disease in some clinical settings. The abnormality is also a significant risk marker for the disease because healthy older adults with this abnormality are more likely to develop Parkinson's disease in the future. The current study will explore the relationship between the appearance of the substantia nigra and measures of body function - focusing on body functions that are known to be altered in Parkinson's disease. The findings will further understanding of this biomarker as a diagnostic tool and risk marker for Parkinson's disease.

The results of this research will be used by the student investigator (Elio Arruzza) to obtain a Doctor of Philosophy degree. This research has been initiated by the researcher Associate Professor Gabrielle Todd.

What does participation in this research involve?

Your participation will involve completing a series of questionnaires and non-invasive and painless tests of body function during one or two appointments. All participants will be asked to complete an online questionnaire and an appointment at the City East Campus of the University of South Australia (approximately 2-2.5 hrs in duration). Some participants will be asked to also complete a neurological examination (30 mins) at Neurology SA (Blackwood) on a different day. Further information about the questionnaires and tests are provided below.

Before Appointment 1:

- Screening questionnaire: You will be asked questions about your health and to determine whether you are eligible to participate in this study.
- Online questionnaire: You will be asked questions about your sleep, vision, mood, physical activity, and gut and bowel function

During Appointment 1:

- Neuropsychological assessment: You will be asked to perform short tests of memory, thinking, and mood. These tests will include, for example, recalling a short story and a sequence of numbers that will be read to you and listing as many words as you can that start with a particular letter (in 1 min).
- Heart rate & blood pressure test: Your heart rate will be measured by attaching non-invasive, stick-on electrodes on your wrists and ankle. Blood pressure will be monitored via a cuff placed on your upper arm. Heart rate and blood pressure will be recorded while you are sitting, lying down, and standing, and while you forcefully breath out. Your breathing rate will also need to be monitored during this time, and this will occur by attaching a small sensor on your abdomen (over your clothing).
- Speech test: You will be asked to read a short paragraph, produce a prolonged vowel sound for five seconds, say the days of the week, say an unusual word (e.g., pataka), and to speak about a specific topic for five minutes. Your speech will be recorded using a microphone and specialised equipment.
- Hand Function: You will be asked to place key-shaped pins into corresponding holes on a grooved pegboard, using your right and left hand.
- Olfaction test: You will be asked to smell pens that contain different scents and to identify the scent from a list of options.
- Transcranial ultrasound: The appearance of a brain structure called the substantia nigra will be viewed with non-invasive transcranial ultrasound. The ultrasound probe will be placed above your ear. The technique is safe, non-invasive, and painless, and involves using the same ultrasound machine and probe that is used on pregnant women.
- Drug use questionnaire: You will be asked questions about use of medications, alcohol, tobacco, e-cigarettes, and illicit drugs.
- Urine sample: You will be asked to provide a small sample of your urine for routine drug screening. The result of the urine test will be recorded, and your urine sample will then be placed in a biohazard bin (within 10 mins of you providing the sample).

During Appointment 2:

- Neurological examination: A neurologist (Associate Professor Robert Wilcox) will ask you questions about your health, and you will be asked to perform a range of movements (e.g. walking for 5 m, alternating hand movements, and tapping your heel).

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids research staff or participants jumping to conclusions.

Participants who complete the study will be reimbursed ($30 for attending one appointment and $50 for completing two appointments). Reimbursement will be made via a generic gift card provided at the conclusion of the appointment.

What are the possible benefits of taking part?

While this study will not provide you with any direct benefits, your participation will contribute to a greater understanding of how the appearance of the substantia nigra relates to aspects of body function. The findings will further understanding of this biomarker as a diagnostic tool and risk marker for Parkinson's disease.

What are the possible risks and disadvantages of taking part?

There are minimal risks associated with participating in this research project. The above-described tests are non-invasive, safe, and painless, and are used in routine clinical practice.

You should be aware that any information gathered from you regarding illicit drug use could in principle be obtained by court order or police request: that is, it could be required to be handed over to the police and used as evidence in a court of law against you. However, this is very unlikely. We will make every effort to ensure that any information that you provide will remain confidential. A code will be assigned to you prior to the first appointment and any data collected thereafter will be linked to your code (not your name).

If you find any of the tests or questionnaires distressing, please let the researcher know and the appointment can be stopped. If you require out-of-hours support, please contact Lifeline by phoning 13 11 14.

Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

What will happen to information about me?

By signing the consent form, you consent to the named research staff collecting and the above-described personal information about you for the research project. Your privacy and confidentiality will be maintained at all times during this project. Any information obtained in connection with this research project that can identify you will remain confidential subject to the court or police processes mentioned above. You will be assigned a participant number (e.g. c-001) and all relevant data collected about you will be labelled with this number and not your name. Information will be stored safely and securely in a locked filing cabinet and on password protected computers and servers at the University of South Australia. Information and data collected from you will only be used by the researchers working on the study. The results of all tests will not be published in a way that could reveal your identity. All records will be kept for a minimum of 15 years in accordance with the requirements of the Australian Code for the Responsible Conduct of Research (2018), Research Ethics Policy Directive (2020), and General Disposal Schedule No. 28. Please note that non-identifiable data collected in this project may be used in future related projects, for which ethics approval will be sought. In accordance with relevant Australian

and South Australian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

If the neurologist identifies a clinically relevant abnormality, you will be notified of this in writing. The letter will include a description of what the abnormality is and you will be advised to consult your GP. Neurologist investigator A/Prof Wilcox may also include some information for the GP with recommendations for further tests and/or treatment that may be required.

What if something goes wrong?

If you suffer distress, or injuries including psychological injury or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment and support. If you are eligible for Medicare, you can receive any medical treatment required to treat the issue, free of charge, as a public patient in any Australian public hospital.

What happens when the research project ends?

At the end of the research project, the information collected will be analysed and prepared for presentation and publication. This may be through peer-reviewed scientific publications, at scientific conferences, and in the format of a thesis. Only de-identified data will be presented and published. A lay summary of group data, and copies of the resultant publications, will be provided to you at the end of the project via post or email.

Who is organising and funding the research?

The research project is being organised by Associate Professor Gabrielle Todd (University of South Australia). The University of South Australia has contributed funding towards the cost of performing the research project. The researchers are submitting applications to other medical and scientific funding bodies to cover the remaining direct research costs. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

Who has reviewed the research project?

The ethical aspects of this research project have been approved by the Human Research Ethics Committee (HREC) of the University of South Australia as required by the Australian government research requirements, specified in the National Statement on Ethical Conduct in Human Research (2023). This statement has been developed to protect the interests of people who agree to participate in human research studies.

Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the principal researcher on (08) 8302 1979 or any of the following people:

Research contact person

Name	Gabrielle Todd
Position	Associate Professor of Neuroscience, University of South Australia
Telephone	(08) 8302 1979
Email	Gabrielle.Todd@unisa.edu.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, please contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	University of South Australia Human Research Ethics Committee
HREC Executive Officer	Human Ethics Officer
Telephone	+618 8302 6330
Email	humanethics@unisa.edu.au