Participant Information Sheet

PROJECT TITLE: Modulating the shape of brain oscillations to drive clinical benefits in Parkinson's disease.

HUMAN RESEARCH ETHICS COMMITTEE APPROVAL NUMBER: HREC/HRE/2025/0516

PRINCIPAL INVESTIGATOR: Dr George Opie

Dear Participant,

You are invited to participate in the research project described below.

What is the project about?

Parkinson's disease (PD) is one of the most common neurodegenerative disorders, driving significant disability in more than 100,000 Australians. Although several therapies for PD exist, these have many side-effects and tend to lose effectiveness over time. Consequently, next generation therapies that are minimally invasive, low risk and reliable are required. This project will examine how non-invasively modulating specific types of brain activity might be used as an alternative therapy for PD.

Who is undertaking the project?

This project is being led by Dr George Opie and the Neurophysiology of Movement team, with support from the Neurosurgical Research Foundation.

Why am I being invited to participate?

This study requires adults aged over 18 years with a diagnosis of PD, as well as healthy adults. All participants are required to be fluent English speakers, and interested in being involved in neurophysiological research. However, you **cannot** participate if you:

- Have a history of psychiatric disease
- Have been diagnosed with a neurological disorder other than PD
- Have a history of substance abuse
- Have a cardiac pacemaker
- Have metal implants in the skull or body
- Are pregnant
- Suffer from claustrophobia

What am I being invited to do?

Depending on the arm of the study you participate in, the following procedures may be performed.

- **Questionnaires.** You will be asked to complete a series of questionnaires. These surveys will provide us with information on your general health and well-being, mood and quality of life, in addition to hand preference during normal daily activities.
- **Cognitive Assessment.** You will be asked a series of questions that assess cognitive function.
- **Functional tasks.** You will complete tests of motor function that require you to move an on-screen cursor to different targets as quickly as possible, or press keys in response to visual cues. You will also perform a series of movements with a small sensor on your hand or foot.

- **Electrical activity of the brain (EEG).** A cap containing many electrodes will be placed on your head, and small amounts of electrode gel will be added to each electrode. The EEG activity will then be measured by a computer while you open and close your eyes, while you perform motor tasks, and while we apply transcranial magnetic stimulation (see below).
- **Magnetic Resonance Imaging (MRI).** This is a type of medical imaging that uses a magnetic field to generate high resolution images of body structures. During the process, you will lay on a bed within a cylindrical tube and hear a series of beeping and clunking noises. The process will take about 15 mins and will be conducted within the clinical and research imaging centre (CRIC), located in the South Australian health and medical research institute (SAHMRI).
- **Transcranial alternating current stimulation (tACS).** This method applies very weak electrical current to the scalp, the pattern of which mimics natural brain activity (i.e., brain waves). Small electrodes will be placed against the scalp, with the current passing between them while you complete some simple tasks. This technique may produce an extremely mild tingling sensation when it is first applied, but this fades very quickly, and is not painful. Furthermore, sensations will be reduced further by applying a numbing cream to your scalp prior to stimulation. You may also experience a visual flashing sensation, like the lights are being flicked on and off. This is normal and not dangerous.

MRI will be collected at the clinical and research imaging centre, located in Jones Radiology at the South Australian Health and Medical Research Institute (SAHMRI). All other procedures will be performed at the University of Adelaide, within human neurophysiology labs located in room S436, level 4 of the Helen Mayo South building (Frome Rd).

How much time will my involvement in the project take?

All participants will undergo an initial session where MRI will be collected (~ 1 hr duration). For healthy adults, you will then attend two neurological testing sessions (total of 3 sessions). In contrast, PD patients will attend five neurological testing sessions (total of 6 sessions). Each neurological testing session will be ~3 hrs in duration. As a thank you for your participation, you will be offered an honorarium of $25 per session completed.

Are there any risks associated with participating in this project?

For participants with PD, testing will be applied both on (2 sessions) and off (4 sessions) medication, and it is possible that removal of medication may worsen symptoms. Consequently, we ask that all PD patients provide written confirmation that their general practitioner or neurologist believes removal of medication for the required periods is acceptable. Any patient judged to be unsuitable for removal of medication will be excluded from participation.

It is not expected that there will be any side-effects as a result of receiving brain stimulation in this study. However, some people have reported mild headaches in other studies that have used these techniques. In addition, some people may experience skin irritation or tingling/burning sensations beneath the stimulating electrodes. Participants are asked to advise researchers if they experience any of these or any other side effects.

While MRI is incredibly safe when appropriate screening is applied, participants should be aware of the following:

- The procedure involves being placed in a confined space, which may induce panic or stress in those prone to claustrophobia.
- Shifts in the magnetic field can cause muscle twitches that are not dangerous, but may be uncomfortable.
- The scanner makes loud noises, but hearing protection will be offered by the technicians
- Some participants may experience heating
- If a participant has an implanted foreign object or medical device they are unaware of, or do not inform the researchers of, it may undergo movement or stop working.

Some of the tests completed during this study may have prognostic value (e.g., assessments of cognitive function). If results from any such tests fall below a clinically validated cut-off (i.e., a score of 23 for MoCA), participants will be contacted and asked to follow-up with their general practitioner. In addition, surveys completed as a part of this study involve questions relating to mood, wellbeing and quality of life. While these cannot be used for diagnosis,

participants will be contacted (via email or phone) for follow-up based on their scores from these tests. In addition, we refer any concerned individuals to the following resources:

- **Mental Health Triage Service** (13 14 65)
  - 24 hours, 7 days a week
  - Can provide advice and information in a mental health emergency or crisis situation
  - Staffed by mental health clinicians
  - Will assess and refer to acute response teams where appropriate.

- **Lifeline** (13 11 14, www.lifeline.org.au)
  - 24hours, 7 days a week
  - A mental health and self-help resource
  - Phone line counselling, all day and night, every day of the year
  - You can download or phone order a self-help tool kit on a range of issues and you can call the service for referral information.

As a matter of policy, we exclude any persons from our study who have had a seizure or suffer from epilepsy, or have a family history of epilepsy. Also, anyone who has had a stroke, metal implants in the skull or body, or cardiac pacemakers are excluded from these experiments. You should not participate if you have a history of alcohol or substance abuse or psychiatric illness or a history of brain injury. You will be asked to fill out a series of questionnaires to assess your suitability for the study. Please advise the experimenters if any of these medical conditions apply, or if you have any questions about your involvement.

What are the potential benefits of the research project?

We cannot and do not guarantee that you will receive any personal benefits from this study. The results of these tests do not provide any prognostic or diagnostic information relevant to you or your treatment and will not affect the clinical management of your PD. However, the results of this study will help us better understand how PD influences the brain, and how we might use non-invasive brain stimulation to treat PD.

Can I withdraw from the project?

Participation in this project is completely voluntary. If you agree to participate, you can withdraw from the study at any time

What will happen to my information?

Your data will be stored in a re-identifiable state, meaning that it will be allocated a unique code and have personal identifiers removed. It will be stored on a password protected University computer for a period of 7 years, and only accessed by members of the research team. Following this period, your data will be permanently deleted. Although information gained from this study may be published in scientific journals, presented at scientific conferences, and be included in research theses, and made publicly available on open-access data servers, your personal information will be kept confidential, and you will not be identified by any means. In addition to the processes described above, data may otherwise be discoverable through processes of law or for assessing compliance with research procedures. You have a right to access the information collected and stored by researchers about you. You also have a right to request that any information with which you disagree be corrected. You have a right to ask that any stored data be destroyed, but should be aware that information which has already been derived from this data may not be able to be destroyed.

Your information will only be used as described in this participant information sheet and it will only be disclosed according to the consent provided, except as required by law.

Who do I contact if I have questions about the project?

If you have any questions about the study, or would like to register be involved, please contact:

Dr George Opie: Ph 8313 4157, Email: george.opie@adelaide.edu.au

What if I have a complaint or any concerns?

The study has been approved by the Human Research Ethics Committee at the University of Adelaide (approval number HRE/2025/0516). This research project will be conducted according to the NHMRC National Statement on Ethical Conduct in Human Research 2007 (Updated 2018). If you have questions or problems associated with the practical aspects of your participation in the project, or wish to raise a concern or complaint about the project, then you should consult the Principal Investigator. If you wish to speak with an independent person regarding concerns or a complaint, the University's policy on research involving human participants, or your rights as a participant, please contact the Human Research Ethics Committee's Secretariat on:

Phone: +61 8 8313 6028

Email: hrec@adelaide.edu.au

Post: Level 3, Rundle Mall Plaza, 50 Rundle Mall, ADELAIDE SA 5000

Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

If I want to participate, what do I do?

If you would like to participate in this study, please register your interest with the research person who provided you with this information sheet.

Yours sincerely,

Dr George Opie
A/Prof John Semmler
A/Prof Lyndsey Collins-Praino
Mrs Ekaterina Voevodina