The SPIN Registry:

Systematic Profiling in Neurological Conditions Registry

PARTICIPANT INFORMATION SHEET

What is the purpose of the study?

This research project aims to develop a comprehensive profiling system for people living with a neurological condition, which will provide clinicians with a tool to help tailor their treatment plan, as well as inform the development of individualised interventions. You are invited to take part in this research project as you are someone living with or without a neurological condition.

This participant information sheet provides specific details about the research project. In particular, it discusses the assessments and procedures involved in the project. This information will help you decide if you want to participate in this research project.

Please read through all the information carefully. If you do not understand or want to know more about specific aspects of the study, please contact the coordinator of the project, Mrs. Manja Laws (contact information below). It is worthwhile discussing with a relative, friend or your neurologist/neuropsychiatrist prior to participating in this research project.

Participation in this research project is voluntary. If you do not wish to participate in this research project, you do not have to. You will receive the best possible care regardless of whether you participate in this research project.

If you decide you want to take part in the research project, you will be asked to sign the consent form provided with this document. By signing this document, you are indicating to us that you:

- Understand the information provided in the participant information sheet and consent form
- Consent to participate in the research project
- Consent to undertake the assessments and procedures that are described
- Consent to the use of your personal and health information as described

You will be provided with a copy of this participant information sheet and consent form for your personal records.

Study Location

This study will be conducted remotely via online surveys and all materials required will be send to you. For those who choose to participate in the voluntary on-campus assessments, these will be conducted in Perth, Western Australia, at Edith Cowan University (Joondalup Campus).

Who is conducting this research?

This study is being conducted by researchers at Edith Cowan University.

Project Sponsor

This project is supported by MSWA.

What does participation in this research involve?

Participant Eligibility: To be included in the study you either have been formally diagnosed with a neurological disorder by your doctor or are living without a neurological condition. You need to be between 18 and 85 years of age and able to follow verbal or written instruction. You will also need to have been on a stable medication regime (no medication changes) for four weeks prior to assessment procedures.

Written and Informed Consent: Prior to the commencement of assessment procedures or any engagement in study measures you will be required to sign a study consent form (provided with the participant information sheet). By signing this consent form, you are indicating that you have read and understood the requirements of the research project, have had all questions answered to your satisfaction and are freely agreeing to participate.

Study Assessments: You will be asked to undertake a wide range of assessments every 12 months, covering a variety of areas. Study assessments will mainly consist of questionnaires that can be completed at home. You may be asked to wear a wearable device that measures your sleep and provide a small blood or saliva sample. You will be given the opportunity to undertake optional assessment procedures, however these will need to be undertaken in specialised facilities by trained professionals at Edith Cowan University (Joondalup). A detailed overview of study assessments is provided below for your review.

Online assessments consist of the following:

- *Demographics Questionnaire*: We will ask you a few questions about yourself, such as your date of birth, education, medical history, comorbid conditions, employment status, current medication and nonmedication therapies.

- *Cognitive Assessment:* Cognitive assessments may be used to assess your memory, attention, problem-solving, information-processing speed, cognitive flexibility, and dual tasking abilities. Some of these assessments will be timed. Assessments will be administered by trained researchers via teams or over the phone, at a time of your choosing, and take approximately 1.5 hours to complete.

- *Pain Assessments*: We will ask you to fill out three questionnaires to document any pain you might be experiencing. These forms should take no longer than 5 minutes to complete

- *Social Assessments*: We will ask you to fill out a variety of questionnaires which look at social behaviour, loneliness, personality, empathy and social network size and diversity. These assessments will take approximately 5 minutes to complete.

- *Sleep and Circadian Assessment:* You will be asked to either wear an activity monitor on your wrist and/or waist for seven consecutive days and nights, as well as complete a sleep diary every day for seven days. The activity monitor measures your movement while you are awake or asleep, allowing for the measurement of sleep quality and restless sleep. Alternatively, we may provide you with a head worn device to measure your sleep. We will also ask you to place a temperature sensor on your bedside table for seven days to record the light and temperature conditions in your usual sleep environment. You will also be asked to complete questionnaires to measure your sleep quality and efficiency.

- *Lifestyle Assessments:* You will be asked to complete questionnaires about your lifestyle, including level of physical activity, nutritional intake and socialisation engagement, occupation status and education level. These questionnaires should take no longer than 60 minutes to complete.

- *Quality of Life Assessment*: You will be asked to complete questionnaires on your quality of life. These questionnaires are estimated to take no longer than 30 minutes to complete.

- *Activities of Daily Living (ADL) Assessment*: You will be asked to complete two questionnaires and an assessment of how well you conduct regular activities of daily living, including self-care, working, managing finances and social interaction. These assessments are estimated to take no longer than 10 minutes to complete.

- *Speech/Communication assessments:* We may ask you for a 15 minute 'speech sample', which will involve you speaking freely about a happy and a sad event for one minute, followed by a 10-minute conversation about a topic of your choice. This speech sample will be recorded for future analysis.

- *Biological Assessment*: You may be asked to provide a small amount of saliva (2mL), which equates to less than half a teaspoon. The saliva sampling procedure should take no longer than 10 minutes and involves you using the pictured device. Instructions will be provided with the materials. The sample will be stored in an unidentifiable manner in a restricted-access freezer, according to your specifications on the below consent form.

- *Background interview*: To better understand the experience of people living with neurological conditions we would like to ask participants to volunteer for a 60-90-minute interview. Areas covered in the interview will be your experiences of living with a neurological condition. This conversation will be recorded and will be conducted via secure digital communication (such as Teams). Should you be happy to participate we would organise this for a day of your convenience.

- *Mood Assessments:* We may ask you to fill in a variety of questionnaires capturing your mood over the last week and ad hoc. These questionnaires are expected to take 5 minutes to complete.

We expect that the above-described measures may take approximately 4 hours to complete with breaks as required.

All materials will be delivered to you and collected via paid delivery service at no cost to you.

The below described measures capture the 'voluntary on-campus assessments' you are invited to participate in, should this be feasible for you:

- *Motor Assessment:* Postural stability (balance) may be assessed using a specialised device called a Neurocom, which measures your balance while moving and remaining still under different sensory conditions (e.g., eyes closed). You will be required to wear a harness during testing to stop you from falling as the assessments can be difficult. A Timed Nut and Bolt Test may be used to assess your manual dexterity. Grip strength may be assessed using a calibrated Hand Grip Dynamometer device. Dual tasking may be assessed using a Walking While Talking Test. Lower limb function may be measured by the 30 Second Chair Rise Test. These assessments are expected to take 30 minutes to complete, will be administered by trained investigators at Edith Cowan University (Joondalup) and may be videotaped for future analysis.

- *Dual Energy X-ray Absorptiometry (DXA):* You will be given the opportunity to undertake a body composition (DXA) scan which measures your bone content, fat and muscle mass. The scan involves lying down on a scanning bed with your arms at your sides and your hands facing the table. A researcher will help you to assume the required position if necessary. During the scan you will be exposed to a small amount of radiation (1-5 microSieverts, uSv), which is below that of other x-ray procedures, as well as below the amount of radiation you would be exposed to when travelling interstate via air travel. The scan takes approximately 3 minutes and the whole procedure takes between 10 to 30 minutes.

- *Extended Biological Assessment:* You may be asked to provide a small amount of blood (41.5ml), which equates to less than 3 tablespoons. The blood test will require you to fast and will be taken in the morning. Blood will be taken by a qualified staff member (with certified phlebotomy training). The blood sampling procedure should take no more than 10 minutes. Your sample will be stored in an unidentifiable manner in a restricted-access freezer, according to your specifications on the below consent form

Should you be interested in the above descripted voluntary on-campus assessments please indicate this in the consent form. You will be contacted to organise these assessments on a day of your convenience.

Do I have to take part in this research project?

Participation in this 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, without any prejudice. Your decision on whether or not to take part, or to withdraw at any point during the study, will not affect your normal treatment or your relationships with those treating you.

If you decide to take part in this research project, a consent form can be found following this document, which should be signed and returned as instructed. You are encouraged to keep a copy of your consent form and this information sheet.

What are the alternatives to participation?

You do not have to participate in this research project. Declining to participate in this research project will in no way affect your normal treatment or your relationships with your treating clinician, community associations or the research team.

What are the benefits of participating in this research?

Many of the assessments used in the study are not readily available to the public and are expensive to undertake. These assessments can provide you with important information on your health and wellbeing. These results, with the exception of genetic information, can be made available to you at your written request. Your participation will mean that we collect information about your health and function which could be useful for your doctor and healthcare team in providing you with the best treatment. There are also potential indirect benefits associated with participation in this research project. We expect that the information we collect within this study will inform the development of new interventions to improve the quality of life for people living with neurological conditions. With your permission, we would like to contact you about these future interventions developed as a result of the data gathered from this study. Please note: by indicating on the consent form below that you are happy to be contacted about future trials, you are providing us only with permission to contact you, it does not mean you have to participate in future trials. We will provide you with information and seek your consent before you enter any future trials, and you are under no obligation to participate in these.

What are the possible risks and disadvantages of taking part?

Time commitments are associated with this study. For those who attend voluntary on campus assessment there will be travel (however we have dedicated parking bays for participants). There are some risks associated with assessments in the study. Please read the following sections carefully for information on risks associated with motor tests and blood sampling tests.

What information do I need to know about answering the take home questionnaires?

We are asking you to answer a range of questionnaires which look at multiple aspects of your life, such as social network, activities of daily living and quality of life. Though highly unlikely, some people might experience discomfort after answering these questionnaires. Should you experience any discomfort we

encourage you to talk to a family member or your treating physician. Should this not be an option for you please find contact details for the following helplines:

Lifeline Australia: 13 11 14

Beyond Blue: 1300 22 4636

What information do I need to know about performing motor assessments?

If you are participating in the voluntary on-campus assessments, you will be asked to perform a series of motor function assessments that may require you to perform multiple successive muscle contractions. You may experience minor fatigue and muscle soreness on the day or days to follow. However, this is normal and will pass. Furthermore, you will receive as many breaks as needed throughout the testing process in an attempt to reduce the occurrence of these effects as much as possible.

What information do I need to know about Dual Energy X-ray Absorptiometry (DXA)?

If you are participating in the voluntary on-campus assessments, you will be asked to undergo a DXA scan. These are routine tests; however, they carry a small risk as it involves the exposure to ionizing radiation. The level of radiation exposure is exceedingly small (1-5 microSieverts, uSv), in comparison to the annual radiation dose in Western communities (approximately 3000 uSv). The radiation exposure during a DXA scan is also small in comparison to the amount of radiation exposure during an airline flight (approximately 80 uSv) or during a typical x-ray (30-40 uSv).

What information do I need to know about the sleep assessment?

An ActiGraph is a small, lightweight device, slightly larger than a watch that is worn on the wrist or waist. The device measures movement (acceleration) and light exposure, with the aim of measuring the length of time spent asleep and the quality of your sleep. While the devices are small and light, they may cause minor discomfort while sleeping. The head worn device could cause minor discomfort, particularly if you are not used to wearing any head coverings.

What information do I need to know biological assessments?

Some possible risks associated with blood testing include bruising and bleeding around the needle/lancet site, dizziness and fainting. In very rare cases, haematoma and infection can occur. For both the saliva and the blood collection it is important to note that you will be provided with the all the necessary equipment as well as detailed instructions for collection methods and hygiene guidelines.

What information do I need to know about DNA (Genetic) Testing and Storage?

This part of the information sheet is to give you more information about how your DNA (genetic) material will be analysed and stored at Edith Cowan University.

What is DNA?

DNA is the abbreviation for deoxyribonucleic acid, which are chemical compounds that make up your genetic material, or genes.

Your genes are inherited from your (biological) parents. The genes you inherit from your parents may lead to a medical problem in early or late life. A gene mutation is an alteration to your DNA and may also be associated with a particular disease.

Testing of your genes or genetic material can provide us with information on what may happen to your general health, or perhaps that of your family, either now or in the future.

Why is DNA tested?

DNA testing is undertaken in medical research. It helps us learn more about diseases and what causes them. In doing so, it may assist in clinical management of patients with such diseases. In this study, we will be conducting an exploratory analysis of your DNA. This means that we will be looking for new (novel) genetic information, the clinical significance of which is not yet known and will need to be verified in other studies. This means that we will not be able to provide you with the results generated from these analyses, as we don't yet know how these potential genes could influence health and disease.

Informed consent

DNA testing will only be carried out if you have given your consent in writing.

We recommend that you give careful consideration to the important information set out in this information sheet. If you have any questions, we encourage you to ask the person enrolling you. Before you give your consent, we want you to be sure and clear about all aspects of the testing and storage of your genetic material.

How will my DNA be obtained in this study?

In this study, DNA will be extracted from cells in the blood/saliva sample that you provide as part of the study. Once extracted from your blood/saliva cells, DNA appears as a clear fluid (like water). For storage purposes, it is kept in a small plastic tube and labelled only with an ID number. This sample is stored in an access restricted freezer at Edith Cowan University. There is no cost to you for storing your sample.

DNA can be stored for an indefinite period of time. Therefore, if your sample remains in storage, it may be used in future tests and research that is currently unknown.
Given this, we give you the option of instructing us on how your DNA is to be used and stored. If you agree to participate in this study and when you sign the consent form, you will be asked to select one of the three options for using and storing your blood/DNA sample:

1. Test and then store my blood/saliva/DNA sample indefinitely for research in the field of neurological conditions.
2. Test and then store my blood/saliva/DNA sample indefinitely for future unspecified research.
3. Discard my blood/saliva/DNA sample after it has been tested for the specific purpose of this study.

As we will be using your DNA sample for exploratory (meaning novel) research rather than targeting known disease carrying genes we will not be able to pass results of this specific component of the study on to you. The results will be published in a group format (de-identified).

There may be the rare circumstance when the Chief Investigator is placed in the position where disclosure of your genetic material may be required by law. This may be as a result of a court order, for example. Wherever possible, you will be informed if this should occur.

Sometimes blood components, including DNA, are sent to other research institutions within Australia and/or overseas. If this occurs, your blood/saliva/DNA sample will be labelled with an identified code or number, which only the members of this research study team will be able to trace back to you. If collaborative research is undertaken with other research institutions, please be assured that your identity will not be disclosed to individuals working in these other research institutions. Should you not wish to have DNA sample be made available for collaborative research please advise the project coordinator in writing.

What if I change my mind?

You have the right to withdraw your consent and blood/saliva/DNA sample at any time. If you wish to have your blood/saliva/DNA sample withdrawn, please notify the project coordinator in writing. Be assured that we will promptly discard your blood/saliva/DNA sample in an appropriate manner.

You may wish that your blood/saliva/DNA sample be discarded upon your death, in which case we ask that you make such provisions by advising the project coordinator in writing either at the commencement of or at any stage during the conduct of this study.

What will happen to my test results?

Your test results will be de-identified and stored on password-encrypted computers for a maximum of fifty years. Access to your data in digital as well as hard copy format is restricted to study personnel. The files containing hard copies of your assessments will be stored in lockable filing cabinets in the study coordinators office at Edith Cowan University. These filing cabinets will only be accessible to study investigators. After fifty years, your data will be permanently destroyed.

Your biological samples will be de-identified and stored in locked freezers in a secure laboratory at Edith Cowan University. We ask that you allow your biological samples to be stored and used for future studies. This is very important to advance research into markers of disease progression in neurological conditions.

All test results will only be used for research purposes. These results will be communicated via research publications and seminars in general terms. All participant data will be de-identified prior to presentation and will be presented as a cohort to ensure your confidentiality.

Will my tests results be used for a student research project?

Student researchers will be involved in this research and may use your test results for their research project. Importantly, none of your test results will be identifiable. Students involved in this research project will also have to be approved by the Edith Cowan University Human Research Ethics Committees.

Will I receive my data at the end of the research project?

The general research results will be provided in a group format (de-identified). Should you wish to receive an overview over your results, with the exception of genetic results (detailed above), please inform the project coordinator in writing.

If we discover any significant information at any stage during the study that may impact on your health, we are obliged to inform your doctor. In the consent form following this information letter, you will be given the choice of the following options regarding how these results are handled: we can provide you with a letter that you can then take to a doctor of your choosing, or we can send a letter directly to your nominated doctor.

Will my data be kept confidential?

Please be assured that any information obtained about you as part of this study will be treated with the strictest of confidence. Clinical information along with your study data will be available to researchers only and will be securely stored in lockable filing cabinets located at Edith Cowan University. All clinical data will be transferred onto password-protected computers and securely stored on password encrypted hard drives and servers. All collected data will be de-identified by the lead investigators.

All biological samples will be de-identified (allocated a code) and securely stored in lockable freezers in a secured-access facility at Edith Cowan University.

Sometimes test results will be sent to other research institutions within Australia and /or overseas. If this occurs, your test results will be de-identified, which means that only the members of this research study team will be able to trace them back to you. If collaborative research is undertaken with other research institutions, please be assured that your identity will not be disclosed to individuals working in these other research institutions. Should you not wish to have your test results be made available for collaborative research (or sent to certain locations) please advise the project coordinator in writing.

What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available that may influence your current treatment. This information will be communicated to you.

Can I have other treatments during this research project?

It is understood that during a research project, other opportunities for treatments may arise. You can choose to undertake these treatment options; however, we do ask that you report to the project coordinator any changes in your medications during the study period as that will help us to ensure the research information is correct.

What if I withdraw from this research project?

If you decide to withdraw from the research project, please notify a member of the research team before you withdraw. This notice will allow that person or the project coordinator to discuss any potential health risks or special requirement linked to withdrawing.

If you withdraw your consent during the research project, the study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that any data collected by the research team up to the time you withdraw will form part of the research project results. If you decide that you do not want your results used for the research project, you must communicate this in writing to the project coordinator.

Who has reviewed this research project?

An independent group of people called a Human Research Ethics Committee (HREC) reviews all research in Australia involving people. The ethical aspects of this research project have been approved by the HREC at Edith Cowan University (study identification number 2019-00970-LAWS).

What if I have complaints?

If you suffer any injuries or complications as a result of the research project, you should contact the study team as soon as possible. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. If you would like to speak to an independent party about this research project, you may contact the Edith Cowan University Human Research Ethics Committee (phone: (08) 6304 2170, email: research.ethics@ecu.edu.au). Kindly mention the study identification number (2019-00970-LAWS) in your communications to help with the processing of your request.

Contacting the research investigators?

We are happy to answer any questions you may have now, or at any point throughout the study. Please contact the study coordinator with your queries:

Mrs. Manja Laws
Phone: (08) 6304 2423
Email: m.laws@ecu.edu.au or spin@ecu.edu.au

If you have concerns about the research and wish to speak to an independent party, you may contact:

Edith Cowan University Human Research Ethics Committee
Phone: (08) 6304 2170
Email: research.ethics@ecu.edu.au

Who do I contact if I would like to take part in the SPIN Research Program?

If you would like to participate in the SPIN Research Program please contact the SPIN Research Team through email using the contact details below. A member of the research team will make contact with you within 24-48 hours.

Email: spin@ecu.edu.au

Thank you for taking the time to read through this information booklet.

Coordinating Principal Investigator

Prof Moira Sim (Edith Cowan University)

School of Medical and Health Sciences Edith Cowan University
270 Joondalup Drive
JOONDALUP WA 6027
Phone: 6304 3504

Investigators

Prof Simon Laws (Edith Cowan University), Prof Mandy Stanley (Edith Cowan University), Prof Amanda Devine (Edith Cowan University), Prof Chris Abbiss (Edith Cowan University), Prof Natalie Ciccone (Edith Cowan University), Prof Joanne Dickson (Edith Cowan University), Dr Travis Cruickshank (Edith Cowan University), Dr Johnny Lo (Edith Cowan University), Dr Mitchell Turner (Edith Cowan University), Mrs Manuela Laws (Edith Cowan University), Ms Kirsten van Rijn (Edith Cowan University), Ms Madeline Griffith (Edith Cowan University), Ms Leah Dempsey (Edith Cowan University), Ms Rachel Orbuck (Edith Cowan University), Mrs Kate Turner (Edith Cowan University), Ms Lidija Milicic (Edith Cowan University), Ms Rachel Batten (Edith Cowan University).