PARTICIPANT INFORMATION SHEET
RESEARCH PROJECT

Study Title: ACT Multiple Sclerosis (MS) Cohort Study
Protocol Number: ACT Health: ETH.2019.00081 ANU: 2020/047
Sponsor: The Australian National University

Principal Investigators:

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- Dr Anne Bruestle, John Curtin School of Medical Research (JCSMR), the Australian National University (ANU), Canberra, Australia. Phone: 02 6125 9009. Email: anne.bruestle@anu.edu.au
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Research Sites: The Canberra Hospital
The Australian National University

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish. You can also ask the Study Coordinator at any time to discuss any part of the study with you.

1. What is the purpose of this study?

The aims of the ACT MS Cohort Study are to:

a. Understand more about the population of people living with MS in the ACT and surrounding regions – how many people, the age and sex distribution, what type of MS they have, their current treatment etc.
b. Learn about what factors affect the health and wellbeing of people with MS, and compare those factors and those effects for people who do not have MS. This includes genetic, environmental, personal, lifestyle, treatment and psychological factors.
c. Collect and store blood samples from people living with and without MS in the ACT region for future research including to identify blood chemicals and genetic factors that can be used to monitor and/or predict disease activity and responses to treatment.

d. Create a database of people in the ACT region – both living with MS and without MS - who may be interested in participating in future research studies aiming to improve the health and wellbeing of people with MS.

The ACT MS Cohort Study is part of a program of work at the Australian National University called Our Health in Our Hands (OHIOH). The Australian National University (ANU) launched the Grand Challenge funding scheme in 2017 and Our Health in our Hands (OHIOH) was awarded the inaugural grant which aims to transform health care by developing new personalised health technologies and solutions in collaboration with people living with MS, clinicians and health care providers. With a focus on multiple sclerosis and diabetes, there are four integrated, multi-disciplinary research programs within OHIOH involving researchers from across the ANU and ACT Health: Genomics and Bioinformatics, Big Data, Biomarker Discovery and Monitoring Devices, and Patient Experience.

2. Why have I been invited to participate in this study?

You have been invited to participate in this study because you are a resident living in the ACT region and you are either:

a) 18 years or older and have a confirmed diagnosis of Multiple Sclerosis (MS), or of a Clinically Isolated Syndrome (CIS, i.e. a single episode of symptoms suggestive of MS that could, possibly, develop into MS in the future). Participants can have any type of MS including Primary Progressive MS (PPMS), Relapsing Remitting MS (RRMS), Secondary Progressive MS (SPMS) or Progressive Relapsing MS (PRMS).

b) 18 years or older without a diagnosis of MS or any known signs or symptoms of MS and are the same sex and age as the participants who are living with MS in this study. In this study people without MS are compared with people living with MS to examine factors associated with MS onset and progression.

3. What if I don't want to take part in this study or if I want to withdraw later?

Participation in this study is **voluntary**. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the medical staff caring for you.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason and without any negative consequences. Please tell the study team if you wish to withdraw from the study.

If you withdraw from the study prior to the results being submitted for publication and no longer wish for your de-identified information to be used, it will be removed from the participant database. If you no longer wish for any of your blood samples to be used, they will be destroyed. However, if you withdraw after results from the study have been submitted for

publication, your de-identified information and any results from the analyses of your blood samples will be included in the publication.

Alternatively, if at any time you decide to withdraw from this study, you can choose to have the research team retain the information you have provided along with any of your blood samples which will then be used in ongoing research, e.g. data analysis and publications.

4. What does this study involve?

After you have read this information sheet, you will be invited to discuss the study with the Study Coordinator and anyone else you wish, such as your family and friends, GP and/or neurologist. Once your questions about the study have been answered to your satisfaction, you will be invited to participate in the ACT MS Cohort Study by signing a written consent form.

If you consent to participate in this study, we will need to obtain information about you and your health over several sessions, and collect a blood sample, either at the ANU or at your place of residence. The one-on-one interview can be conducted with the Study Coordinator either face-to-face or over the telephone. You will also be asked to complete online questionnaires. The maximum session time will be two hours and the Study Coordinator will offer regular breaks, as required, during each session.

You can reduce the time of each session if you wish, and you can determine the amount of time you require between sessions.

You can decline to answer any question or to provide personal information at any time during the study without having to give a reason. All questions and questionnaires are standardised and routinely used in epidemiological research with people living with MS.

Participation in the study will involve:
(i) Providing information about yourself. This includes your age and date of birth, your ancestry, the health of your grandparents, parents and children, your education and past and current employment. We will also seek information about your past medical history (including any major illnesses) and the medical history of your immediate family members. Other questions will examine your psychological health and wellbeing (including depression, anxiety, sleep, stress, cognition, quality of life and fatigue), and smoking. You will also be asked to complete a questionnaire about your diet, and your height, weight, the circumference of your waist and hip and blood pressure will be measured.

(ii) Assessment of your current health. As far as is possible, this information will be obtained from your medical records (including your clinical notes and MRI scans for participants with MS only), held at Canberra Health Services (CHS) formerly known as The Canberra Hospital (TCH) and/or with your GP and treating doctor/neurologist. If your medical records are at CHS, study researchers will access your records on the hospital computer system (with your permission) and transfer the relevant information onto the electronic database for the purposes of this study. If you are not a patient at CHS, you can provide consent for study researchers to

contact your treating doctor/neurologist to obtain your medical information. We will only access your medical information with your consent.

Where any information we need is not included in your medical record, we will ask you to provide the missing information (e.g. about your current health conditions and, for people living with MS, your past and current MS symptoms, signs and treatment).

We will assess your functioning using the EDSS (Expanded Disability Status Scale). The EDSS rates eight functional systems including muscle weakness, limb mobility, balance, speech, body sensations, visual function and problems with thinking and memory.

(iii) A blood sample will be collected. A qualified person will collect 60 mL of your blood. DNA will be extracted from the whole blood sample, and serum (the watery part of blood) and DNA will be stored at the Australian National University. The blood samples will be identified only by your participant identification number and the date of the blood draw. Serum and DNA will be analysed along with the samples for other participants in the ACT MS Cohort Study for known or potential factors that may affect or indicate disease activity, and/or disease progression or wellbeing of people with MS, and the genetic factors that may moderate these relationships.

You will be asked whether you provide consent to be contacted by ANU researchers to hear about future ANU MS-related studies, however, you are not required to participate in such studies and can change your mind about participating at any time without having to give a reason. Any sub-studies that seek to use blood data for purposes other than those stated in this participant information sheet, or seek new blood collection, will be the subject of additional ethics variations/applications.

This study is longitudinal, which means that information will continue to be collected from you over time. Each year or following a clinical relapse, we will ask you to complete questionnaires, have body measurements and undertake some of the tests (e.g. the EDSS), and have a repeat blood sample taken. We are very conscious of not overloading participants and you can refuse any data collection at any time while still staying in the study. Researchers will, where you provide your on-going consent, monitor you across time (this study currently has ethics approval until 2024, however this will be dependent on ongoing funding which will be sought through grant applications, internal resources and philanthropic donations).
In general, participation will proceed as follows:

Session 1. Study introduction and preparation
The Study Coordinator will introduce the study to you and, when your questions have been answered to your satisfaction and if you would like to participate, you will be asked to sign the study consent form. You will then be given some questionnaires and asked to complete them at home and bring them to the next study appointment.

Session 2. Baseline appointment
Ideally, the Baseline appointment will occur within one month of an appointment with your treating doctor/neurologist if you are a person living with MS, or once you have completed the study questionnaires if you are participating as someone who does not have MS. At this session, we will go over the questionnaires and the Study Coordinator will fill in any missing information with your help. Study measurements will be completed (e.g. height and weight) and you will complete the questionnaires relating to your psychological health and wellbeing (including depression, anxiety, sleep, stress, cognition, quality of life and fatigue) with the Study Coordinator. At this appointment a blood sample will be taken (as described above).

Session 3. Annual appointments and/or following a clinical relapse
Each year (again, ideally within a month of a neurology review for people living with MS), or following a clinical relapse, we will ask you to complete similar questionnaires (of course some questions will not need to be asked again, e.g. age, ancestry, etc.) and have similar measurements to those taken at the Baseline (entry to the study) appointment.

One aim of the ACT MS Cohort study is to develop a database of participants who are interested and available to contribute to new MS research studies being conducted by researchers at the Australian National University, particularly as part of the Our Health in Our Hands project (https://www.anu.edu.au/research/research-initiatives/our-health-in-our-hands). The consent form offers an option for you to consent to being contacted about new ANU MS-related research studies as they commence. Any new studies will have a separate ethics approval process with separate participant information sheets and consent forms. You will be free to choose whether you want to participate in any future studies or not, and can change your mind about participating at any time without having to give a reason.

You have the right to access the information collected and stored by the researchers about you. Please contact Dr Jo Lane (phone: 02 6125 1485, email: jo.lane@anu.edu.au) or Dr Anne Bruestle (phone: 02 6125 9009, email: anne.bruestle@anu.edu.au) if you would like to access your information.

5. How is this study being paid for?

This study is funded by the ANU. It is part of the Our Health in Our Hands Grand Challenge Program run by the ANU. Participation in this study will not cost the participants anything. Participants will be given a parking permit when visiting the ANU. Participants will not be paid for their involvement.

6. Are there risks to me in taking part in this study?

There are limited risks associated with participating in this study.

a. Discussing your background, medical, environmental and psychological information, or the assessment of your current MS symptoms (for participants with MS) may contribute to uncomfortable feelings e.g., feeling distressed or sad. If this occurs, you can discuss this with the Study Coordinator or seek support from a support person, the MS support service (MS Connect) or Lifeline (contact information for support organisations is on the last page of this Participant Information Sheet).

b. There are minor risks of bruising, redness, swelling and bleeding with a blood collection. Blood will be collected only by study staff who are qualified and experienced in blood collection to minimise this risk.

There will be no direct benefits to you or your health as a result of your participation in the ACT MS Cohort Study. However, the information obtained from this study may ultimately lead to a better understanding of MS that could lead to improvements in the quality of life of people living with MS.

7. What if something goes wrong?

If you have any problems associated with your participation in this study, please contact Dr Jo Lane (phone: 02 6125 1485, email: jo.lane@anu.edu.au) or Dr Anne Bruestle (phone: 02 6125 9009, email: anne.bruestle@anu.edu.au).

8. Who is organising and funding the research?

This study is being conducted by the study team headed by Professor Christian Lueck, Professor Robyn Lucas, Dr Anne Bruestle, Professor Ted Maddess and Dr Jo Lane. The study is funded by the ANU. No investigator or member of the research staff will receive any personal financial benefit from your involvement in this study. The study researchers declare no personal conflict of interest relevant to the undertaking of this study.

9. How will my confidentiality be protected?

Each researcher involved in this study will maintain strict confidentiality regarding all information obtained from individual participants, caregivers, physicians and clinic data.

To maintain confidentiality, participants will be assigned a unique identification number after they have provided written consent to participate in the study. Only the Principal Investigators will have access to the secure database that links participant names to their identification numbers. The Study Coordinator can provide the de-identified participant identification numbers to other members of the research team as required without revealing any personal or identifying details about the participants, e.g. their name, date of birth, address. For example, blood samples collected will record only the participant identification number and the date and time of blood collection.

Data collected in this study will be used to better understand how genetic, personal, environmental, psychological and lifestyle factors contribute to or modulate disease activity and progression and affect the health and wellbeing of people living with MS.

If you consent to be contacted for possible participation in future sub-studies, none of the information collected for this ACT MS Cohort Study will be released to the investigators in the sub-study without your permission. Any new sub-study will undergo separate ethical review processes and will require separate participant information sheets and consent forms.

Signed consent forms and de-identified questionnaires and notes will be separately stored in locked filing cabinets at the National Centre for Epidemiology and Population Health

(NCEPH) at the ANU in a locked room in a security-pass secured building. All data will be entered into an electronic database using the participant identification number only (no identifying data) on a password-protected computer in a password-protected file at NCEPH. Participant data will be stored for at least five years after the date of the final publication arising from this research. Following this time, de-identified electronic data and participant forms will be archived at NCEPH, and any data (hardcopy or electronic) that can identify a participant will be destroyed.

Blood samples will be stored labelled only with identification numbers in a pass-secured freezer in the John Curtin School of Medical Research building at the ANU. Blood samples will be stored indefinitely or until they are completely used up.

10. What happens with the results?

Outcomes of this study may be presented at scientific meetings and MS conferences, published in medical journals and made available on the ANU OHIOH website (http://www.anu.edu.au/research/research-initiatives/our-health-in-our-hands). Copies of journal articles will also be available from the study researchers upon request.

In any publication, information will be provided in such a way that individual participants cannot be identified.

11. What should I do if I want to discuss this study further before I decide?

When you have read this information, the Study Coordinator, Dr Jo Lane, will discuss it with you and answer any queries you may have. You are also able to take this information away with you and discuss it with your family, friends or any other person you choose. If you would like to know more at any stage, please do not hesitate to contact Dr Jo Lane (phone: 02 6125 1485, or email: jo.lane@anu.edu.au).

12. Who should I contact if I have concerns about the conduct of this study?

This study has been approved by the ACT Health and ANU Human Research Ethics Committees (protocols ETH.2019.00081 and 2020/047). If you have any concerns or complaints about the conduct of this study, you can contact the researchers listed at the top of this sheet.

If you do not feel comfortable discussing matters with study staff, you may contact the Committee secretariat who is nominated to receive complaints about research projects. You should contact the secretariat on 02 5124 7968 or ethics@act.gov.au.

If you have any concerns or complaints about how this research has been conducted, please contact:

Ethics Manager
The ANU Human Research Ethics Committee
The Australian National University
Phone: 02 6125 3427
Email: Human.Ethics.Officer@anu.edu.au

In collecting your personal information within this research, the ANU must comply with the *Privacy Act 1988*. The ANU Privacy Policy is available at https://policies.anu.edu.au/ppl/document/ANUP_010007 and it contains information about how a person can:

- Access or seek correction to their personal information;
- Complain about a breach of an Australian Privacy Principle by the ANU, and how the ANU will handle the complaint.

Support organisations:

Lifeline
Lifeline Crisis Support: 13 11 14
24-hour support service
Website: http://www.lifeline.org.au

MS Connect
MS Support Service: 1800 042 138
8:30 to 5pm Monday to Friday
Website:
https://www.ms.org.au/support-services/ms-connect

Thank you for taking the time to consider this study.

If you wish to take part, please sign the attached consent form.

This information sheet is for you to keep.