Participant information sheet

Study title: Comparing Australia and New Zealand MS Populations Project

Locality: Canterbury District Health Board

Lead investigator: Dr Deborah F MASON

You are invited to take part in a study looking at the effects of multiple sclerosis (MS) treatments in people with MS. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will need to give your consent in the second question of the online survey. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 7 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

This project aims to explore the long-term effects of MS medications, also called disease modifying therapies or DMTs by comparing people with MS living in Australia and New Zealand because access to MS treatment programs differs between the two countries. We will examine the links between MS medication use and other long-term health outcomes including disability, employment and socio-economic outcomes such as income and educational opportunities.

This collaborative study is being conducted by:

- Dr Deborah Mason, a neurologist from Canterbury District Health Board New Zealand
- Professor Bruce Taylor, a neurologist from the University of Tasmania, Australia
- Dr Suzi Claflin, a post-doctoral research fellow from Menzies Institute for Medical Research, Australia

This project has been funded by MS Research Australia. No member of the research team will receive a personal financial benefit from your involvement in this research project.

Please feel free to contact Dr Suzi Claflin if you have any questions about this study.

Email: suzi.claflin@utas.edu.au

This study does not require Health & Disabilities Ethics Committee approval. However the study has been reviewed by the CDHB research office and we have consulted with Te Komiti Whakarite.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You have been invited to take part in this study because you participated in a national prevalence study of multiple sclerosis in New Zealand conducted 2006 and at that time expressed an interest in participating in future research studies.

We intend to enrol 1400 participant into this study: 700 participants recruited in Australia and 700 participants recruited in New Zealand.

Ideally, you will have access to the internet to take part in this study where you will log on to a secure website to complete the web-based questionnaires.

There are two questionnaires: the **Lifestyle and Medical History Survey** and the **Cost Diary**.

- **Lifestyle and Medical History Survey**: during this survey, you will be asked to tell us about yourself (e.g. your date of birth, height, etc.), and about your MS history, including year of onset, symptoms, and treatments. You will also be asked to give information on your employment status, income, and education. This survey takes approximately 45 minutes to complete. **All participants in this study will complete this survey.**
- **Cost Diary**: collects information about the cost of MS for people with MS, their support networks, and support services. The Cost Diary is made up of six 20-minute surveys taken over the course of six months (1 survey per month for six months). **These questionnaires are optional for participants.** You will be asked if you are willing to complete the Cost Diary in the Lifestyle and Medical History Survey consent form (the first question in this survey).

The research group is also interested in the data collected by the New Zealand government on healthcare, because it gives important information about the cost of MS in New Zealand. In the consent form below, you will also be asked for permission to access your MS-related health data, using your **National Health Index (NHI) number**. **You are free to say no to these requests.** Your response to these questions will not affect your ability to participate in this study. This data will be treated with the strictest confidence. Please see below for further details on data storage.

Both surveys can be completed over multiple sessions and you can re-enter the survey using the original link that was emailed to you.

If you find navigating a computer or the internet difficult we would still like you to take part in this study. Please contact Dr Suzi Claflin (see email address above) and she will arrange for a member of the study team to call you and arrange a time to complete the questionnaires over the telephone.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

It is unlikely that you will receive any benefit from taking part in this research. Although it is hoped that the information obtained from your participation in this study, will provide valuable information to assist future treatment management in people with MS. No risks related to your participation have been identified.

WHO PAYS FOR THE STUDY?

There are no costs associated with participating in this research project. You will not be paid for your participation in this research project.

WHAT IF SOMETHING GOES WRONG?

We do not foresee any potential risks associated with your participation in this study.

If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT ARE MY RIGHTS?

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.

By signing or electronically agreeing to the consent form you consent to the relevant research staff collecting and using personal information about you for the research project.

Any information obtained in connection with this research project that can identify you will remain confidential and will only be used for the purpose of this research project. Your collected information will be labelled with a unique study code only, and not your name. Information collect only be disclosed with your permission, except as required by law.

All study documentation will be maintained in a secure area which is only accessible to authorised staff. Information stored at the Canterbury District Health Board and the University of Tasmania will be held for a period of 10 years and then disposed of according to their policy for disposal of confidential data. Data collected by the New Zealand government will be de-identified and securely stored in firewall-protected computer files at the University of Tasmania for 10 years and then destroyed.

An Internet "online portal" has been created for the questionnaires. The data you enter is transferred over a secure Internet link. You will need to provide a valid personal email address before being granted access to the online portal. If you wish, you may create a personal e-mail account which does not identify you (i.e. genericname@e-mailprovider.com) just for participation in this study.

You will receive personalized link to access the online portal. Your email address will only be accessible to specific study personnel who will need access to your email address in the event you experience any issues with using the online portal. Every reasonable and adequate effort will be made to keep your email address secure and confidential. This electronic data will be stored at the University of Tasmania in secure computer files.

Information obtained during the study is subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorized representatives of the University of Tasmania, this organization (Canterbury District Health Board), , or as required by law. By signing or electronically agreeing to the consent section, you authorize release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

Your participation in this study is voluntary and you may choose to leave the study at any time. We will still use the information collected before your withdrawal.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Name:	Jane Eagle
Position:	Research Nurse & Coordinator
Phone:	03 378 6130
Email:	Jane.Eagle@cdhb.health.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone:	0800 555 050
Fax:	0800 2 SUPPORT (0800 2787 7678)
Email:	advocacy@hdc.org.nz

For Maori health support please contact :

Te Puna Oranga (CDHB Maori Health)

Phone:	03 378 6160

Canterbury
District Health Board
Te Poari Hauora ō Waitaha

Consent Form

Study title:	Comparing Australia and New Zealand MS Populations Project		
Locality:	Canterbury District Health Board		
Lead investigator:	Dr Deborah F MASON	Contact phone number:	03 364 0940

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.

I have been given sufficient time to consider whether or not to participate in this study.

I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.

I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.

I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.

I consent to the research staff collecting and processing my information, including information about my health.

I agree to an approved auditor appointed by any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.

I understand that my participation in this study is confidential and that no material that could identify me personally will be used in any reports on this study.

I understand the compensation provisions in case of injury during the study.

I know who to contact if I have any questions about the study in general.

I understand my responsibilities as a study participant.

If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed. Yes ☐ No ☐

I agree to be contacted for future research being conducted by the MS study group	Yes ☐	No ☐
I wish to receive a summary of the results from the study.	Yes ☐	No ☐
I wish to complete the COMPANZ Cost Diary.	Yes ☐	No ☐
I give the research team permission to access my national medical records to gather data on the cost of MS in New Zealand: public hospitalizations, public outpatient care, and prescription medications.	Yes ☐	No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Email address: _____

Contact Phone number: _____