

## EXPLANATORY STATEMENT

**Project Title:**

**The Multiple Sclerosis Australian Women's Midlife Years (MS-AMY) study**

Project ID: 45712

Study funding: Multiple Sclerosis Australia Project Grant 24-PG-0155

This information sheet is for you to keep.

My name is Associate Professor Vilija Jokubaitis, and I am the head of the Multiple Sclerosis (MS) Genomics, Women's Health and Prognostics Research team at Monash University. I am conducting this study with my colleagues Professor Susan Davis, the Director of the Women's Health Research Program at Monash University and Dr Rakib Islam who are experts in Public Health, together with the assistance of Professor Helmut Butzkueven and Associate Professor Anneke van der Walt, MS-specialist neurologists, and Ms Molly Bond.

You are invited to take part in this study. Please read this Explanatory Statement in full before deciding if you wish to participate.

### **The purpose of this research.**

The main aim of the study is to understand physical health and psychological, sexual and socioeconomic wellbeing of Australian midlife women living with MS, and how this compares to women who do not have MS. This study is only for women living with MS, as diagnosed by a neurologist.

Part of understanding the health needs of midlife women is knowing what happens to women's hormones between the ages of 40 and 69 years, including the impact of menopause. Surprisingly this remains uncertain. In order to have a full picture of the health and wellbeing of Australian women living with MS at midlife we would like you to participate whether you have any health concerns besides your MS or not.

### **Possible benefits**

This study will help us understand the health, and health needs of Australian Women living with MS, and how this compares to women who do not have MS. This will give us information about general health and wellbeing and what women see as health issues. It is a world first in determining how women's hormone changes during this life phase (perimenopause, menopause, post-menopause) impact their MS, their quality of life, and it will tell us about health care gaps, and what is needed in future research in women's health.

### **What does the research involve?**

If you agree to participate you will be asked to complete our online questionnaire. Your answers will be collected by Roy Morgan Research as a Third Party, on behalf of Monash University. The questionnaire asks you about your health in general, any medical conditions, your menstrual cycle and or menopause, mood, and medications. It also asks specific questions about your MS, including the type of MS you have, your MS symptoms, and the medications you use to manage your MS or MS symptoms. The questionnaire will take approximately 30-45 minutes to complete. You don't have to complete it all at once. You can come and go to the site and the system will remember where you are up to. Some of the questions are of a sensitive nature. You can call the study co-ordinator on 1800 384 844 if you have any questions or concerns.

### **You can withdraw from the research**

By completing and submitting the questionnaire you are consenting to your responses being included in the study analysis. However, being in this study is voluntary and you are under no obligation to participate. Furthermore, if you do consent to participate, you may withdraw up to four (4) weeks after completing the survey. If you do decide to withdraw either we can keep the data you have already provided or you can call our study co-ordinator on 1800 384 844 to withdraw all your data from the study.

### **Payment**

You will receive a \$25 e-gift card for completing this survey in full. To receive this, you will need to provide your email address at the end of the survey. The e-gift card will be provided as a link in an e-mail message from Roy Morgan Research. Please note that to be eligible for an e-gift card, survey responses must be complete and meet quality standards. Responses that are incomplete or fail data quality checks will not be eligible. Each individual is only eligible to participate in the study and receive the incentive once.

### **Confidentiality**

Once collected, your data remains confidential. For research purposes, you will be identified in the data set by a code and not by your name or personal details. Your personal details will be stored separately from your completed questionnaire. We have asked for a contact phone number as the questionnaire asks about your emotional and physical wellbeing. If your answers indicate that you may be severely distressed we will contact you to ensure you have access to care if needed. We may also contact you if we need to clarify any essential information. When results of the study are published no identifying information will be used.

### **Storage of data**

Data collected will be stored in accordance with Monash University regulations. De-identified, electronic data will be kept on the University computer system, in a password protected electronic file. Data will be destroyed 7 years after the completion of the study.

If you agree to be contracted for future research study participation, your name and contact details together with your study code (but not study data) will be provided separately to the study team. Your personal details will be kept on Monash University computer systems, in a password protected electronic file.

### **Inconvenience/discomfort**

The main inconvenience of this study is the time required to complete the survey. However, some women may feel distressed when answering some personal questions. This is a voluntary study so if you think you may feel distressed by completing the questionnaire then you may decide not to participate in it.

If after completing the questionnaire you feel very down or upset, then please consider seeking assistance from your general practitioner. You may also find the following organisations helpful:

Beyond Blue – You can talk with a trained mental health professional 24 hours per day, 7 days per week (1300 224 636; [www.beyondblue.org.au](http://www.beyondblue.org.au)).

Lifeline – A 24 hour counselling service (13 11 14).

1800RESPECT – A 24 hour help line for women experiencing domestic violence or sexual abuse (1800 737 732; [1800RESPECT.org.au](http://1800RESPECT.org.au))

Safe Steps – A 24 hour domestic violence help line (1800 014 188; [safesteps.org.au](http://safesteps.org.au))

**Results**

If you would like to receive a summary of the research findings, please contact us via

email [ms-amy@monash.edu](mailto:ms-amy@monash.edu)

or visit our websites

<https://www.monash.edu/medicine/translational/neuroscience/research/jokubaitis-group> or

<http://womenshealth.med.monash.edu.au>.

A summary will be posted on our websites.

**Future Research**

At the end of the survey, you will be given an option to provide your personal details if you are happy to be contacted to participate in future research projects related to this one. You are under no obligation to do so.

Whether or not you choose to provide your details for future research, this will not impact your participation in the current study.

**Complaints**

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics (MUHREC):

Executive Officer

Monash University Human Research Ethics Committee (MUHREC)

Room 111, Building 3e

Research Office

Monash University VIC 3800

Tel: +61 3 9905 2052      Email: [muhrec@monash.edu](mailto:muhrec@monash.edu)      Fax: +61 3 9905 3831

Thank you,

**Associate Professor Vilija Jokubaitis and Professor Susan Davis**

A/Prof Jokubaitis Ph: 9903 0880

Prof Davis Ph: 03 9903 0827

Email: [ms-amy@monash.edu](mailto:ms-amy@monash.edu)

## **Consent Form**

### **Project Title: The Multiple Sclerosis Australian Women's Midlife Years (MS-AMY) study**

I understand that I have been asked to take part in the Monash University research project specified above. I have read the Explanatory Statement and I understand that I will be asked to complete questionnaires about my multiple sclerosis, health, wellbeing, medications, menstrual cycle, psychological and sexual wellbeing. I consent to my responses being included in the data analysis of this study.

I understand that my participation is voluntary, and that I can withdraw at any stage.

I understand that no information I have provided that can lead to my identification will be disclosed to any other party or in any reports on the project. I also understand that I will remain anonymous at all times in any reports or publications from the project.

I understand that data from the survey will be kept in secure storage and accessible only to the research team and destroyed after 7 years.

I understand that I may be contacted for clarification of my answers. I also understand that I will only be recontacted for future research if I have consented to this.

I understand that, at the end of the survey, I will be given an option to provide my personal details if I am happy to be contacted to participate in future research projects. I also understand that I am not under any obligation to do so.

**<ACCEPT BUTTON>**