

Participant Information Sheet (M-PreM@home)

The Menarche-to-PreMenopause (M-PreM) substudy

1 Introduction

You have been a participant in the Australian Longitudinal Study on Women's Health (also known as Women's Health Australia) since 1996 – thank you! We have collected valuable data about Australian women and now we want to find out how we can improve and personalise healthcare.

You expressed an interest in a new substudy of Women's Health Australia): the Menarche-to-PreMenopause (M-PreM) substudy. You will be asked to do a small number of measurements and provide a saliva sample, which will be used for genetic research. 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.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. Your participation in Women's Health Australia is not affected by whether or not you decide to take part in the M-PreM substudy.

2 What is genetic research?

Genes are made up of DNA – the chemical structure carrying your genetic information that determines many human characteristics, such as the colour of your eyes or hair. Researchers study genes in order to understand why some people have a certain condition, such as diabetes and asthma, and why others do not. Understanding a person's genes may also explain why some people respond to a treatment or experience a side effect, while others do not.

3 What is the purpose of this research?

Women are at greater risk of poor health than men as they age. These conditions include heart disease, diabetes, asthma, muscle weakness, and cognitive impairment. This could be due to one or a combination of factors in a woman's life. Therefore, the purpose of this research project is to examine how reproductive (e.g. age at menarche or first period), sociodemographic (e.g. education level, where you live), lifestyle, and genetic factors influence risk of poor health in women.

4 Who is running this study?

This study is being run by Professor Gita Mishra at the University of Queensland and the University of Newcastle, and has been funded by the National Health and Medical Research Council.

5 Why have I been invited to participate in this study?

In your most recent survey, you indicated that you were interested in the M-PreM study. This study is not suitable for you if you: are pregnant or receiving treatment for a reproductive cancer.

6 What if I don't want to participate 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 wish to participate and it will not affect your relationship with Women's Health Australia. You can leave the study at any time without giving a reason and without consequences of any kind. You can also specifically withdraw your biological samples at any time without consequences of any kind. If you do withdraw your biological samples, you can choose to destroy all stored samples and/or unpublished data that has been obtained from using the samples. Note that data that are already deposited in an international data repository or published will not be withdrawn and destroyed.

7 What does this study involve?

If you agree to take part, you will be posted a package containing a questionnaire, saliva collection kit, measuring tape, physical activity monitor, and a sleep diary. You can request this package by calling Women's Health Australia.

Your participation will include:

- **Short questionnaire** – You will be asked questions about when you last had something to eat or drink, your menstrual cycle status, respiratory symptoms, and recent use of medications and health behaviours that affect your lung function.
- **Saliva collection** - you will be asked to provide 2ml of saliva, which will be used to extract DNA for genetic analysis.
- **Body size measurement** – your height, weight, and waist, hip, arm, and thigh circumference will be measured.
- **Physical activity monitor and sleep diary** – You will be asked to wear a small physical activity monitor (4.5cm x 2.5cm) on your thigh and complete a sleep diary for 8 days. The physical activity monitor will be attached at the end of the health check and you will be provided instructions on what to do and how to return the device at the end of the 8 days.
- **Menstrual cycle diary** – If you have been diagnosed or treated for polycystic ovary syndrome, you will be asked to complete a menstrual diary for 3 months.

8 What are the possible benefits of taking part?

Research results from this study are unlikely to be of any immediate and specific benefit to you. The data from this study will be analysed and future medical discoveries may result from your participation. This will help improve and personalise medical treatment and care for women overall.

We will, however, send you the results of your physical activity and sleep pattern. If you are concerned about any of these results, we encourage you to seek advice from your GP.

9 What are the possible risks and disadvantages of taking part?

- You may feel uncomfortable with a particular measurement/test. If you do not wish to answer a question or do a test or measurement, you may skip it.
- It may be possible to trace your genetic sequence back to you, however, this is very unlikely because your genetic data and personal information will be kept in physically separate and secure locations.
- It is also possible that the genetic analysis may reveal information that is important for your health care. You can decide whether or not you wish to be contacted if this situation arises.

10 What will happen to the information collected about me?

- All personal, questionnaire and genetic information collected for the study remains confidential in accordance with the National Health and Medical Research Council (NHMRC) ethical guidelines and the Australian 1988 Privacy Act.
- Your personal details, questionnaire data and genetic data will all be stored separately.
- The data you provide in this study will be linked to the questionnaire data collected by Women's Health Australia in previous and future surveys.
- The only link between your personal details and your other data is your participant ID number. Linking your personal details and other data using this number is restricted to authorised members of the Women's Health Australia research team at the University of Newcastle.
- All other questionnaire and genetic information data about you will be de-identified (i.e. will not contain identifying information, such as your name, address, and date of birth) and stored securely at the University Queensland.
- Your information will be stored indefinitely at these two sites.
- This information may continue to be valuable to researchers many years into the future, and may be considered for use in future projects. These projects will require approval by the relevant ethics committees before they begin.
- Your genetic information (not your biological sample), sleep patterns, physical activity data, and some of your questionnaire information (but not your name, address or date of birth) may eventually be put into an international data repository. Information in the repository will only be available to researchers from around the world who are approved to study how genes, sleep, or physical activity cause a variety of health conditions.
- Your data will be combined with the data from many other women before analysis so there will be no way of identifying you as a participant. Results of this research project may be presented in scientific or public articles and talks, but your identity will not be revealed.

11 What will happen to my biological sample?

We will use your saliva sample to extract your DNA and analyse a small number of genes which are likely to be associated with determining the age when your period starts, other reproductive characteristics, and the development of heart and metabolic diseases. The analysis of these gene cannot be used for diagnosis right now. However during the course

of this research project, we may discover new information that is important for your health care. You will be asked whether you wish to receive the results (this may require you to have the test repeated in a clinical laboratory). If you agree, we may contact you if such a situation arises.

12 Will I receive any payment if I participate in this study?

You will not receive any payment for your participation.

13 Will I be given the results of the research project?

The results of the research project may be presented in scientific or public articles and talks. We will not report the study results in any way that could identify you. Only grouped and summarised results will be reported. We will not publish any information that could identify any particular person.

14 Sample repository (Long term storage of samples)

Your DNA will be stored indefinitely for future research projects as part of the Women's Health Australia in collaboration with Professor Gita Mishra that may or may not be related to this project. All future projects will require approval by the Human Research Ethics Committee with oversight of Women's Health Australia. The DNA that you provide (but not your personal details) may be made available to other researchers working with Professor Mishra to study different health conditions, some of whom may have commercial interests. If you consent to participate, you will be donating your saliva freely for these purposes and waive any claim to commercial rights arising from this work. Your DNA will be stored securely at the University of Queensland Institute for Molecular Biosciences.

Your DNA sample will be stored in tubes with a barcode label containing your project ID number (not the Women's Health Australia participant number you receive on emails and letters). This means that your samples may be re-identifiable, however the likelihood of this happening is very low. You can have the samples destroyed at any time by contacting the Women's Health Australia.

15 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Metro South Health and Health Service HREC.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

16 Further information and who to contact

If you want any further information concerning this project, you can contact Women's Health Australia on 1800 068 081 (Freecall) or email info@alswh.org.au.

If you have any complains about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact the Metro South Health and Health Service Human Research Ethics Committee (EC00167) (Approval number HREC/2019/QMS/52052):

Contact Person: MSH HREC Coordinator
Phone: 07 3443 8049
Email: MSH-Ethics@health.qld.gov.au

17 How do I participate?

If you are interested in participating in the M-PreM study, please contact Women's Health Australia on 1800 068 081 (freecall) or email info@alsw.org.au to request a package or to get more information.