

Prof Gita Mishra, Dr Ellen Wessel  
The University of Queensland  
Herston Road, Herston, QLD 4006  
(07) 3346 5224  
[g.mishra@sph.uq.edu.au](mailto:g.mishra@sph.uq.edu.au)  
[e.wessel@uq.edu.au](mailto:e.wessel@uq.edu.au)

## Participant Information Statement

### The Genetic variants, Early Life exposures, and Longitudinal Endometriosis symptoms Study (GELLES)

You have been a participant in Women's Health Australia since 2013 – thank you! Over this period, we have collected valuable data about Australian women, and now we want to find out more about endometriosis through a new substudy - the **Genetic variants, Early Life exposures, and Longitudinal Endometriosis symptoms Study (GELLES)**. You are invited to participate in GELLES. You don't have to have endometriosis to be involved – in fact, our study needs both women with and without endometriosis.

To take part, you will be asked to complete an online survey, which will take approximately 30-60 minutes. You will also be asked to provide a saliva sample, which will be used for genetic research.

Before you decide whether or not you wish to participate, 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 GELLES is completely voluntary. If you don't wish to take part, you don't have to. Your participation in Women's Health Australia will not be affected by whether or not you decide to take part in the GELLES substudy.

#### **1. Why are we doing this research?**

Endometriosis is a common disease where tissue similar to the lining of the uterus grows outside the uterus on other organs, causing scarring and pain. Endometriosis may cause painful periods, heavy periods, and pain during sex and when going to the toilet. Some women are so severely affected by the disease that they struggle physically and emotionally with their everyday lives. Research from Women's Health Australia shows that an estimated 1 in 9 women under the age of 45 in Australia will be diagnosed with endometriosis. This means that you likely know someone with endometriosis.

Very little is known about what causes endometriosis and who might be most at risk of developing the disease. A person's genes, their family history, and their health and experiences during childhood and adolescence might tell us a lot about who is most likely to get endometriosis. GELLES is planning to look at a person's genes and health across their life. We want to find out more about why endometriosis develops, so that women can be diagnosed earlier and have better treatments.

#### **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 or asthma, and why others don't.

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. Who is running this research?**

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 Medical Research Future Fund. The full research team includes:

- Dr Ellen Wessel, School of Public Health, The University of Queensland
- Dr Ingrid Rowlands, School of Public Health, The University of Queensland
- Dr Sally Mortlock, Institute for Molecular Bioscience, The University of Queensland
- Professor Jenny Doust, School of Public Health, The University of Queensland
- Professor Annette Dobson, School of Public Health, The University of Queensland
- Dr Marina Kvaskoff, French National Institute for Health and Medical Research
- Ms Megan Ferguson, School of Public Health, The University of Queensland

### **4. Who can participate in this research?**

All women from the 1989-95 cohort of Women's Health Australia who completed the latest survey in 2019 are being invited to participate in this research. As mentioned above, you do not need to have endometriosis to participate.

### **5. What will you be asked to do?**

If you agree to participate, you will be asked to:

1. Complete a confidential online survey, which will take approximately 30-60 minutes to complete. The survey includes questions about your health and wellbeing at different points of your life (including medical conditions and pain), your childhood (including questions about your mother's pregnancy with you, very early childhood, and your relationship with your parents), and your family's health. It also includes detailed questions about your menstrual cycles, including symptoms you might experience during your period.
2. Provide a sample of your saliva for genetic analysis (please refer to sections 8 and 10 for more information). If you consent to providing a saliva sample, you will be mailed a saliva collection kit and instructions.

If you choose to participate by completing the online survey, you are not obligated to provide a saliva sample.

### **6. What choice do you have?**

Participation in this research is entirely your choice. Only those people who give their informed consent will be included in GELLES. Whether or not you decide to participate, your decision will not disadvantage you. Your participation in Women's Health Australia will not be affected by whether or not you decide to take part in the GELLES substudy.

If you do decide to participate and later change your mind, you can withdraw from GELLES at any time without giving a reason, by contacting Women's Health Australia on 1800 068 081 (freecall) or emailing us at: [alswh@newcastle.edu.au](mailto:alswh@newcastle.edu.au) or [info@alswh.org.au](mailto:info@alswh.org.au). You will also have the option to withdraw your data up until data has been provided to researchers for analysis or published.

## **7. What are the possible benefits and risks of taking part?**

Everyone who completes the survey by 5:00 pm AEST on Sunday May 29<sup>th</sup> 2022 will go into the GELLES prize draw<sup>1</sup>, with a chance to win a \$1,000 Prezzy Smart eGift Card to be used online or in-store at 100+ Australian retailers. For more details go to: <https://www.prezzy.com.au/store/#gift-cards>. The eGift cards will be sent via email.

Your contributions will help us to discover more about the possible causes of endometriosis. This is important because health care professionals need ways to diagnose the disease earlier and improve treatment for women.

There's a small risk that you may find some of the survey questions uncomfortable to answer. If you start to feel uncomfortable or upset at any time, you can choose to end the survey (with the option to return later, if you want to). You can also choose to skip questions that you are uncomfortable answering. If you are feeling distressed, you may also like to discuss your feelings with someone at Lifeline (13 11 14) or 1800 Respect (1800 737 732).

### *Providing a saliva sample*

If you provide a saliva sample, it is possible that someone could trace the coded information in a scientific database back to you and your participation in this study. Even without your name or other identifiers, your genetic information is unique to you (like a fingerprint). We think the risk of this happening is very low.

Participation in the genetic component of GELLES may have an impact on your access to health, disability, or life insurance, if information about your participation, or information collected through your participation becomes part of your medical record. This could happen if you choose to discuss your participation with your doctor. This would place the information in your medical records, an area to which insurance companies routinely have access. Insurance companies may consider participation in this genetic study "high-risk", believe that it implies there is a family history of a genetic condition. If you are self-employed, or if you apply for a position in which the employer screens employees for health or life insurance purposes, you may have problems with access to health or life insurance. It is also possible you may be refused employment or be terminated from your current employment if the employer's insurance carrier believes you are a high risk for certain genetic disorders.

Participants in this, or any related studies, cannot claim ownership rights to any medical or scientific product that results from research with their saliva sample. Research results about you as an individual will not be available to you or your GP, nor will it be recorded in your health records.

Lastly, it is 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.

## **8. What will happen to the information collected about you?**

*Survey data:* The survey data collected in this study will be linked with the other data held by Women's Health Australia. As with your regular Women's Health Australia data, your GELLES data will be securely stored and may be made available for future research. All researchers who wish to use Women's Health Australia data, including GELLES data, will need to apply to the Australian Longitudinal Study on Women's

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<sup>1</sup> Prize draw: run November 8<sup>th</sup> 2021 – May 29<sup>th</sup> 2022, drawn June 1<sup>st</sup> 2022. Winner randomly drawn from a ballot box will be informed via email. For prize draw terms and conditions, see: <https://alswh.org.au/gelles/information-for-participants/prize-draw-details/>

Health (ALSWH) Data Access Committee and agree to their terms and conditions for use of the data. Researchers may also need to obtain ethical approval for their project from a Human Research Ethics Committee.

*Genetic data:* Your saliva sample will be used to extract your DNA and generate genetic information, which may include sequencing your genome. The study will analyse a small number of genetic variants that are likely to be associated with endometriosis. The analysis of these genetic variants 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 be contacted if research with your DNA reveals some medical condition relating to you or your family. This may require you to have the test repeated in a clinical laboratory. If you agree, we will contact you if such a situation arises.

Your genetic data will be linked with your survey data and other survey and linked health data held by Women's Health Australia.

Data from all participants will be pooled and analysed to examine issues related to women's health and endometriosis. The findings from this study may be reported in publications in scientific journals and in conference presentations and seminars. A summary of results will also be made available in the annual participant newsletter for Women's Health Australia. Individual participants will not be identified in any reports, publications, or presentations arising from this study.

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. You will be asked whether you consent to the storage and use of your saliva sample/DNA for future research projects (see section 10).

Your genetic data (but not your saliva sample) and some of your survey data (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 cause a variety of health conditions.

### ***9. How will your privacy be protected?***

Your privacy is our number one concern. We have processes and systems in place to protect your privacy:

- All personal, survey, and genetic information collected for GELLES remains confidential in accordance with the National Health and Medical Research Council (NHMRC) ethical guidelines and the Australian 1988 Privacy Act.
- Your survey data will be collected using REDCap (an online survey host), with all data securely stored on servers at the Hunter Medical Research Institute in Newcastle, NSW.
- Your personal details, survey data, and genetic data will all be stored separately.
- 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 GELLES survey and genetic data about you will be de-identified (i.e., will not contain identifying information, such as your name, address, or date of birth) and stored securely at the University of Queensland.

- Your data will be combined with the data from many other women before analysis, and findings will only be reported at an aggregate level (i.e., a summary of data from many women). Individual participants will not be identified in any way.
- Results from this research may be presented in published scientific articles and talks, but your identity will not be revealed.

### **10. Sample repository (long-term storage of samples)**

Your saliva sample and extracted DNA sample will be stored securely at the University of Queensland's Institute for Molecular Biosciences indefinitely. Your saliva and DNA samples will be stored in tubes with a barcode label containing a unique barcode number, your project ID number (not the Women's Health Australia participant number that you receive in emails and letters), your first and last initial, and the date at which you initially commenced the survey. This means that your samples may be re-identifiable; however, the likelihood of this happening is very low.

If you consent to the storage and use of your saliva sample/DNA sample for future research, the saliva and resulting DNA data that you provide (but not your personal details) may be made available to future research projects as part of Women's Health Australia in collaboration with Professor Gita Mishra. These projects may or may not be related to GELLES. All future projects will require approval from Human Research Ethics Committees, with oversight from Women's Health Australia. If you provide consent for future research projects, you will not be contacted to provide consent for these projects.

It is possible that some of this research may have commercial interests. If you consent to your saliva/DNA sample being stored and used in future research, you will be donating your sample freely for these purposes and waive any claim to commercial rights arising from this work. Participants in this, or any related studies, cannot claim ownership rights to any medical or scientific product that results from research with their saliva sample. Research results about you as an individual will not be available to you or your GP, nor will it be recorded in your health records.

You can have your sample and/or unpublished data obtained from your sample destroyed at any time by contacting Women's Health Australia. Please note that data that has already been published or deposited in an international data repository cannot be withdrawn or destroyed.

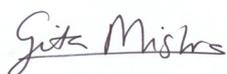
### **11. What do you need to do to participate?**

Please make sure you have read this information statement and that you understand its contents before you consent to participate.

To participate, please click on the link for the survey in your invitation email. You will need to enter your login ID, which you can find in your invitation email. Before you begin the survey, you will be asked whether you consent to participate in GELLES and whether you consent to providing a saliva sample.

If there is anything you do not understand, or if you have questions, please contact Women's Health Australia on 1800 068 081 (freecall) or email [alswh@newcastle.edu.au](mailto:alswh@newcastle.edu.au) or [info@alswh.org.au](mailto:info@alswh.org.au).

Thank you for considering this invitation.



Professor Gita Mishra  
Project Director



Dr Ellen Wessel  
Project Manager

### ***13. Complaints about this research***

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research & Innovation Services, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 4921 6333, email [Human-Ethics@newcastle.edu.au](mailto:Human-Ethics@newcastle.edu.au).