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Participant Information Statement

The Mothers and their Children's Healthcare Experience Study (MatCHES)

You're invited to take part in a new Women's Health Australia substudy – the **Mothers and their Children's Healthcare Experience Study (MatCHES)**.

Before you decide whether you wish to participate, it's 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.

Why have you been invited to join this study?

You've been a participant in Women's Health Australia since 2013 – thank you! We have collected a wealth of data about Australian women. Now we want to find out more about you and your children, specifically your health and healthcare experiences.

Who can participate in MatCHES?

If you're a member of the 1989-95 main cohort, you've given birth to at least one child after 31/12/2014 and they live with you at least part of the time, then you're eligible to join MatCHES.

Why are we doing this research?

Mothers and their children's health are closely linked. Research has shown that women's health prior to and during pregnancy has important impacts on the lifelong health of their children. MatCHES will explore experiences of preventive healthcare from before conception, through to pregnancy and early childhood. We want to examine how effective this care is, and any issues relating to uptake and access.

Who is running MatCHES?

MatCHES is led by Professor Gita Mishra at the University of Queensland and is being run by the Women's Health Australia team at the University of Newcastle. MatCHES has been funded by the Medical Research Future Fund.

What will you be asked to do?

If you agree to participate, you'll be asked to complete an online survey. The online survey will take approximately 30-40 minutes, and will cover questions about your reproductive history, your healthcare experiences before conception and during your pregnancy/ies, and questions about your child/ren and their health, healthcare experiences, and development. You don't have to complete the survey all at once. You can save your answers and return to the survey up until the survey closes.

You will also be asked whether researchers can access and use your child/ren's data from the Medicare Benefits Schedule (MBS), Pharmaceutical Benefits Scheme (PBS), Australian Immunisation Register (AIR), Australian Early Development Census (AEDC), National Assessment Plan (NAPLAN) and other health databases. You can still participate in MatCHES if you don't consent to the researchers accessing your child/ren's data from these databases. Watch this short video to find out more:

<https://youtu.be/DeHVfze2Lag>.

We intend to repeat these surveys every 2-3 years (subject to ongoing funding), and to update external linked data (see above) annually. We want to find out how mothers and their children's health and healthcare experiences change over time.

Your participation is voluntary

Your participation in MatCHES is completely voluntary and there will be no cost to you. If you don't want to take part in this study, you don't have to. Choosing not to take part in MatCHES will not affect your current or future medical care in any way. Your participation in Women's Health Australia will not be affected by whether you decide to take part in MatCHES.

Withdrawing yourself and/or your child from MatCHES

You are under no obligation to continue with MatCHES. You may change your mind at any time about participating in the research. People withdraw from studies for various reasons, and you don't need to provide a reason. If you decide to withdraw yourself from MatCHES, contact Women's Health Australia on 1800 068 081 (Freecall) or email alswh@newcastle.edu.au.

You are under no obligation to continue with the consented release of your child's MBS, PBS, or AIR information. You may change your mind at any time about releasing this information to the study. You can withdraw your consent to release your child's MBS, PBS, or AIR information by completing and signing the 'Services Australia Child Study Withdrawal Form'. You can access this form [here](#). You must supply this form to the research team, if you choose to withdraw your consent for the release of your child's MBS, PBS, or AIR information at a later date. If you withdraw your consent to release your child's information to the study, you will be able to choose whether the study will destroy or retain the MBS, PBS, or AIR information it has collected about your child. You should only choose **one** of these options. Where both boxes are ticked in error or neither box is ticked, the study will destroy all information it has collected about your child.

If you wish to withdraw your consented release of your child's AEDC, NAPLAN, hospital, or emergency department data, please contact Women's Health Australia on 1800 068 081 (Freecall) or email alswh@newcastle.edu.au.

Please note that data about you and/or your child that has already been analysed and/or included in a publication by the study will not be able to be destroyed. In such circumstances, your personal information will continue to form part of the project study records and results. Your privacy will continue to be protected at all times.

What are the possible benefits and risks of taking part?

After completing the survey, you'll receive a \$30 Prezzy Smart eGift card via email. We can't promise you any further personal benefit from participating in this research. However, your contributions will help us to deliver detailed, up-to-date evidence and recommendations that are needed to enable a more tailored, collaborative, and integrated approach to healthcare for women and their children.

There is a small risk that you may find some of the survey questions uncomfortable to answer. Specifically, some of the questions discuss pregnancy outcomes, including miscarriage, stillbirth, and having a child who was born alive but has since died. 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). You can also call The Compassionate Friends 24 Hour National Helpline on 1300 064 068 (local call). This service provides peer support for parents (and siblings and grandparents) after the death of a child.

How will your information be used?

The survey data collected in MatCHES and your child/ren's linked data from health and education databases (if you consent to these being used) will be linked with the other data held by Women's Health

Australia. Data from all participants will be pooled and analysed to examine issues related to preconception, pregnancy, and early childhood healthcare, and women and children's health. The findings from the study may be reported in publications in scientific journals and in conference presentations and seminars. A summary of results will 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 MatCHES.

As with your regular Women's Health Australia data, your MatCHES 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 MatCHES data, will need to apply to the Australian Longitudinal Study on Women's Health (ALSWH) Data Access Committee and agree to their terms and conditions for use of the data.

How will your privacy be protected? Storage, retention and destruction of your information

We have strict procedures to protect your privacy and that of your child/ren. This also applies to external record linkage.

- All personal and survey information collected remains confidential in accordance with the National Health and Medical Research Council ethical guidelines and the Australian 1988 Privacy Act. Your personal information will be securely stored separately from your survey answers and linked data from health databases on servers, or hosted through cloud computing providers, physically located within Australian borders. These locations will be isolated from the internet by firewalls.
- Access to any identifiable data (such as names and contact details) will be restricted to members of the research team and those outlined in this information statement (including those involved in verifying your data in the linkage process), unless you have consented otherwise; or disclosure is required by law in order for us to comply with our regulatory obligations. Furthermore, access to identifiable data requires user authentication for logging into the databases with a username/password combination. All database edits and data entries completed by each user are logged in the database's audit trail. Researchers conducting analyses do not have access to personal information.
- The survey will be completed online through REDCap (Research Electronic Data Capture), a secure web-based database system. REDCap is a purpose-built software application for the conduct and management of medical research surveys and case report forms for clinical trials. The REDCap application is hosted within Australian borders on Hunter Medical Research Institute secure servers, which are both physically and virtually secured. User authentication is required for logging into REDCap. All database edits and data entries completed by each user (including REDCap Administrators) are logged in the project's audit trail.
- The de-identified survey data captured from the online survey will be stored in the research database, separately from participant contact information. For extra privacy protection, different ID numbers will be assigned to these two databases, with the key between the two sets of IDs limited to a small number of staff. Click [here](#) to see the way this works. Copies of de-identified survey datasets are also archived electronically at the Australian Data Archive (a national repository for the curation of research data assets).
- Due to the ongoing nature of the study, the data will be securely retained for at least five years after the study finishes, and stored in accordance with the University of Newcastle's Research Data and Materials Management Guideline (<https://policies.newcastle.edu.au/document/view-current.php?id=72>) or any successor Guideline, The University of Queensland Policy and Procedures (including: [1.60.02 Privacy Management](#), [4.20.06 Research Data Management](#), and [6.40.01 Information Management](#)), and applicable University of Newcastle policy provisions (as

amended from time to time). After the closure of the study and the mandatory retention period, all personally identifying information (such as names, dates of birth and contact details) will be securely destroyed.

- De-identified survey data will continue to be maintained in the Australian Data Archive. Arrangements will also be made at this time about the linked health record data provided to us, for the duration of the study, by national and state governments. At the discretion of the agency which provided the data, it will either be included in the non-identifiable archive, or securely destroyed.

What do you need to do to participate?

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

To participate, please tick 'Yes, I would like to complete the MatCHES survey now' or 'Yes, I would like to complete the MatCHES survey later' when asked the question: Would you like to complete the MatCHES survey?. If you select 'Yes, I would like to complete the MatCHES survey now', you will be redirected to the start of the survey. If you select 'Yes, I would like to complete the MatCHES survey later', you will be sent a reminder email in a couple of days. Before you begin the survey, you will be asked whether you consent to participate in MatCHES. After you complete the survey, you will be asked whether you consent to researchers accessing and using your child/ren's data from health and education databases.

Consenting to data linkage for your child

If you consent to the researchers accessing and using your child/ren's data from health and education databases, you will be asked to sign a consent form. This consent form will authorise the study to access your child's complete Medicare Benefits Schedule (MBS), and/or Pharmaceutical Benefits Scheme (PBS), and/or Australian Immunisation Register (AIR) data from Services Australia. Medicare collects information on your child's doctors' visits and the associated costs, while the PBS collects information on the prescription medications filled for your child at pharmacies. The Australian Immunisation Register is a national register that records vaccines given to people of all ages in Australia.

Your child's personal information within the consent form will be sent securely to Services Australia to authorise the release of your child's MBS, PBS, and/or AIR information to the study. Services Australia will retain the consent form for the life of the study as a record of consent. A copy of the consent form will also be retained by the study for the life of the study. Your child's MBS, PBS, and/or AIR information will be de-identified and stored securely by the study on servers, or hosted through cloud computing providers, physically located within Australian borders. Your child's MBS, PBS, and/or AIR information will not be sent outside of Australian jurisdiction and is governed by the Privacy Act 1988.

Your child's MBS, PBS, and/or AIR information that has been included in de-identified databases will be destroyed after the final publication of the study. As this is a longitudinal study, there is currently no end date for the study.

However, if you withdraw from the study, you can request the destruction of your child's MBS, PBS, and/or AIR information, provided it has not previously been provided to researchers or policy makers (see 'Withdrawing yourself and/or your child from MatCHES'). All information will be securely destroyed at the completion of the study in a manner appropriate to the security classification of the record content.

Power of Attorney, Guardianship and Administration Orders provide people the legal authority to act on behalf of someone else. If you are unable to provide consent for yourself or you are consenting for someone over the age of 14 years, Power of Attorney, Guardianship, or Administration Order may be accepted. Services Australia will only accept a certified copy of an original Power of Attorney (Enduring or

Medical), Guardianship, or Administration order. Services Australia cannot provide the study information without supplied evidence. Statutory declarations will not be accepted.

Services Australia has confirmed that this research and any associated documents have been approved by a Human Research Ethics Committee (HREC) that is registered with the National Health and Medical Research Council (NHMRC) and operates within guidelines set out by the NHMRC.

As our study is asking for consent for external data linkage for children under the age of 14 years, you as the parent must provide consent for your child. If your child is on two separate Medicare cards, both primary card holders must provide consent. The consent form must include both Medicare card numbers for the two cards the child is on and both parent's signatures. Services Australia will only provide data to the study in instances where the primary card holder of that card has consented.

Within this consent form, you will also be able to authorise the study to access your child's AEDC, NAPLAN, hospital, and emergency department data. The AEDC collects information about early childhood development at the time children commence their first year of full-time school, and occurs every 3 years. NAPLAN collects annual assessment data for students in Years 3, 5, 7, and 9. Linkage will be conducted by the Australian Institute of Health and Welfare for AEDC, and state-based Data Linkage Units for hospital, and emergency department data. Linkage for NAPLAN will be conducted by the relevant state education authority themselves, or by an external Accredited Integrating Authorities (as directed by the responsible data custodian).

The study is bound by Commonwealth and State privacy laws and must protect the confidentiality of you and your child/ren's information to the fullest extent possible.

If you have a privacy complaint in relation to the use of your child's MBS/PBS/AIR information, you should contact the Office of the Australian Information Commissioner. You will be able to lodge a complaint with them.

Website: www.oaic.gov.au

Telephone: 1300 363 992

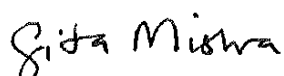
Email: enquiries@oaic.gov.au

Mail: GPO Box 5218, Sydney NSW 2001

Your personal information Services Australia hold is protected by the Privacy Act 1988 and cannot be given to a third party without your consent or where otherwise permitted by law. For more information about privacy, go to servicesaustralia.gov.au/privacy

If there is anything you don't understand, or if you have questions, please contact Women's Health Australia on 1800 068 081 (Freecall) or email alswh@newcastle.edu.au

Thank you for considering this invitation.

A handwritten signature in black ink that reads "Gita Mishra".

Professor Gita Mishra

Project Director

This project has been approved by the University of Newcastle and the University of Queensland's Human Research Ethics Committees, Approval No. H-2012-0256 and H-2021-0383 (University of Newcastle) and 2021/HE002565 (University of Queensland).

MatCHES research team

Professor Gita Mishra, The University of Queensland
Professor Jenny Doust, The University of Queensland
Dr Katrina Moss, The University of Queensland
Professor Deb Loxton, The University of Newcastle
Dr Lisa Buckley, The University of Queensland
Professor Kathleen Bair, University of Technology Sydney
Associate Professor Anthony Herbert, Queensland
University of Technology
Associate Professor Seema Mahrshahi, Macquarie
University
Professor Annette Dobson, The University of Queensland
Professor Craig Olsson, Deakin University
Ms Megan Ferguson, The University of Queensland

Concerns 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.