

NSW Health Pathology Victorian Clinical Genetics Services SA Pathology

## PARTICIPANT CONSENT INFORMATION SHEET AND CONSENT FORM

### The Economic and Personal Impacts of Genomic Testing in Pregnancy

#### Invitation

You are invited to participate in a research study about the economic and psychosocial impacts on families during genomic testing in pregnancy.

#### The study is being conducted by:

A/Prof T Roscioli, Prince of Wales Hospital, Randwick, NSW, 2031

Dr George McGillivray, Victorian Clinical Genetics Service, Parkville, VIC, 3052

Prof D Schofield, GenIMPACT, Macquarie University, NSW 2109

Prof C Wakefield, University of New South Wales, NSW, Sydney, 2052

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.

- 1. What is the purpose of this study?** This study explores the economic and psychosocial impacts of genomic testing in pregnancy. This will be with short questionnaires. You will also be asked to provide consent to access information about you and your child's health care from hospital and emergency records.
- 2. Why have I been invited to participate in this study?** You are eligible to participate in this study because you have been offered clinical genomic testing in pregnancy.
- 3. What if I don't want to take part in this study, or if I want to withdraw later?** Participation in this study is completely voluntary and there will be no cost to you. You should feel under no obligation to participate in this study. Choosing not to take part in this study will not affect your and your child's current and future medical care in any way. Whatever your decision, it will not affect your relationship with the staff caring for you.

You are under no obligation to continue with the research study. You may change your mind at any time about participating in the research. People who withdraw from studies do not need to provide a reason. You can withdraw from the study at any time by completing and signing the '*Parent/Carer Withdrawal of Consent Form*' or by contacting the Research team on (02) 9399 1817 or [pregen@neura.edu.au](mailto:pregen@neura.edu.au). This form is provided with this document and is to be completed by you and supplied to the research team if you choose to withdraw at a later date. If you withdraw from the study, you will be able to choose whether the study will destroy or retain the information it has collected about you. 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 you.

You are under no obligation to continue with the consented release of yours and/or your child's Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) information. You may change your mind at any time about releasing your information to the study.

You can withdraw consent to release yours and/or your child's MBS/PBS information by completing and signing the 'Services Australia Parent Withdrawal of Consent Form'. This form is provided at the end of this document, and is to be completed by you and supplied to the research team if you choose to withdraw your consent at a later date. If you withdraw consent to release yours and/or your child's information to the study, you will be able to choose whether the study will destroy or retain the MBS and/or PBS information it has collected about you or 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 you and your child. If you do withdraw your consent from the study and yours and/or your child's information has already been analysed and/or included in a publication, yours and/or your child's personal information may not be able to be withdrawn or destroyed. In such circumstances, yours and/or your child's personal information will continue to form part of the research records and results. Your privacy will continue to be protected at all times.

- 4. What does this study involve?** The research involves completing two 20-minute questionnaires about your family, within a few weeks after genomic testing is organised and then about 6 months later. The questionnaires will be administered by telephone, virtual meeting (Zoom) or face to face with a study research assistant at a time convenient to you. If you agree, your answers will be recorded to help with transcription. Zoom will not retain a copy of the recording, and it will be stored locally on a secure research server. Interviews conducted on the phone or face to face will be audio recorded locally and then files stored on a secure research server. The Zoom recording or audio recording will be transcribed by the study team under appropriate confidentiality terms and then destroyed once the interview information is transcribed. A brief follow up call will also be organised 1-2 years after the questionnaires in case you have questions or you wish to add information before the end of the study.

Questions will be asked to help us understand the health, financial, and personal impacts of having genomic testing in pregnancy. You will be asked to provide consent for us to access records related to you and your child's health care from hospital and emergency records. Throughout our lives, hospitals, health departments and other groups or organisations collect information about our health and health care (referred to as data). The collection of these data is usually required by law and is securely stored by the service or agency that collects it. This study will collect your child or family member's hospital and emergency records through data linkage which creates links between data stored in different hospitals. With your consent, we will supply the data linkage agency with key fields, including but not limited to your child or family member's name, date of birth and address. The data linkage agency will then create a unique ID for your child or family member and send it to the data custodian responsible for managing hospital and emergency data.

We will collect information about your child or family member from the following databases through third party data linkage agencies:

- Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data
- hospital admitted patients datasets in your state/territory
- Emergency department datasets in your state/territory
- Perinatal datasets in your state/territory

Your child or family member's hospital and emergency records will be merged with the unique ID and sent to us. We will request information from the time of your child or family member's birth to the end of the study. This will give us an accurate record of the healthcare your child or family member has received. If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

**Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) Consent Form** You will also be asked to sign a consent form authorising the study to access your complete Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data as outlined in the MBS and PBS consent form. Medicare collects information on doctor visits and the associated costs, while the PBS collects information on the prescription medications filled at pharmacies. The MBS and PBS data that the study will access include Date of service, MBS Item number, MBS Item description, Provider charge, Schedule fee, Benefit paid, Patient Out of Pocket, Bill type, Hospital indicator and Item category for the MBS data and Date of supply, PBS Item Code, PBS Item Description, Patient category, Patient contribution and PBS Net Benefit for the PBS data. The MBS and PBS consent form is sent securely to Services Australia who holds the MBS/PBS data.

**MBS and PBS Child Consent Forms** You will be asked to sign a separate MBS and PBS child consent form authorising the study to access their complete Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data as outlined in the consent form. If the consent form is signed by a primary card holder only, data relating to a child's Medicare card will be supplied if the primary card holder of that card has consented.

**Services Australia Release of MBS and PBS data**

Services Australia will not provide your personal information to the study without your consent, if you choose to participate. To participate in the study you must complete the 'Services Australia Parent Consent Form'.

Services Australia is not involved in the conduct of this study other than to release your Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) claims information.

If the study is recruiting children under the age of 14 years, a parent must provide consent for their child to participate. If a child is on two separate Medicare cards, both primary card holders must provide consent. The consent form must include both Medicare card numbers the child is on and both parents' signatory. Services Australia will only provide data to the study in instances, where the primary card holder of that card has consented. If a child turns 14 years of age during the recruitment process, the child will be required to complete and sign a separate consent form, this may result in two consent forms for the one child. It will also be accepted to have both parents complete a MBS/PBS consent form if the child is on two cards.

A 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 with participant information without supplied evidence. Statutory declarations will not be accepted.

5. **How is this study being paid for?** The research is being conducted by researchers from the University of New South Wales (UNSW) and GenIMPACT: Centre for Economic Impacts of Genomic Medicine at Macquarie University, in partnership with genetic clinicians around Australia. This collaboration is dedicated to improving health and economic outcomes for families who have genomic testing in pregnancy. This study is funded by the Medical Research Futures Fund (MRFF).
6. **Are there risks to me in taking part in this study?** The information about your experiences obtained from the study may help to inform and improve current practice and policy. Some of the questions asked in this study are sensitive and completing the questionnaires may raise difficult emotions and could be distressing for some participants. If this occurs for you, you will be offered support options which you may access if you wish. Some people who answer questionnaires could become distressed. You will be offered counselling support if this occurs and also be provided with the option of not continuing with the questionnaires if you wish.
7. **What are the alternatives to participation?** You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these include genomic testing without participating in the questionnaires. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.
8. **What happens if I suffer injury or complications as a result of the study?** If you suffer any complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate support.
9. **Will I benefit from the study?** This study aims to further medical knowledge and may improve future treatment for families having prenatal genomic testing, however it may **not** directly benefit you.
10. **Will taking part in this study cost me anything, and will I be paid?** Participation in this study will not cost you anything and you will not be paid for participating.
11. **How will my confidentiality be protected?** Of the people treating you, only your treating doctors and genetic counsellors will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your

permission, or except as required by law. Only the research team named above and their staff will have access to your details and results that will be held securely at Macquarie University. All hard copy questionnaires and consent forms will be stored in locked filing cabinets at GenIMPACT at Macquarie University and will be shredded and disposed of after 7 years from the final project report. The de-identified data will be stored indefinitely. All paper documents, including consent forms, will be destroyed and placed in a secure waste bin. Electronic data and consent forms will be stored in encrypted read-only folders stored within Macquarie University's and UNSW IT infrastructure, accessible only to approved personnel by a login password. Confidential electronic data that can be used to identify any person will be destroyed after 25 years from the final project report. Your personal details, replies to the questionnaires and results will be strictly confidential. To protect your privacy, no identifying individual information will be published. Data related to MBS, PBS, and hospital, emergency, and perinatal datasets will not be used in any future research outside of this approved study unless you provide additional consent. These datasets will be destroyed after 7 years from the publication of the final project report.

Yours and your child's personal information within the consent form will be sent securely to Services Australia to authorise the release of MBS and/or PBS information to the study. Services Australia will retain the consent form for the life of the study as a record of your consent. A copy of your consent form will also be retained by the study for the life of the study. Your MBS/PBS 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 MBS and/or PBS information will not be sent outside of Australian jurisdiction and is governed by the Privacy Act 1988.

12. **What happens with the results?** If you give us your permission by signing the consent document, we plan to discuss/publish the results with the study sponsor for monitoring purposes, peer-reviewed journals, presentation at conferences or other professional forums. In any publication, information will only be provided in an anonymous way to protect your family's identity. Results of the study will be provided to you, if you wish.
13. **What should I do if I want to discuss this study further before I decide?** When you have read this information, the researcher will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact the Research team on (02) 9399 1817 or email [pregen@neura.edu.au](mailto:pregen@neura.edu.au).
14. **Who should I contact if I have concerns about the conduct of this study?** This study has been approved by the Royal Children's Hospital Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research Support Office which is nominated to receive complaints from research participants. You should contact them on, Research Ethics & Governance, The Royal Children's Hospital, Level 4, South Building, 50 Flemington Road, Parkville Vic 3052, Ph: 03 9345 5044.

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.

The study is bound by Commonwealth and State privacy laws and must protect your anonymity and the confidentiality of your information to the fullest extent possible.

If you have a privacy complaint in relation to the use of your MBS and/or PBS 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](http://www.oaic.gov.au)

Telephone: 1300 363 992

Email: [enquiries@oaic.gov.au](mailto:enquiries@oaic.gov.au)

Mail: GPO Box 5218, Sydney NSW 2001

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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](https://servicesaustralia.gov.au/privacy)

**Thank you for taking the time to consider this study.**  
**If you wish to take part in it, please sign the attached consent form.**  
**This information sheet is for you to keep.**



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### CONSENT FORM

#### The Economic and Personal Impacts of Caring for families having Genomic testing in Pregnancy (PreGen Prospective Study)

1. I,.....  
of.....  
agree to participate in the study described in the participant information statement set out above.
2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the study aims and possible risks of the investigation, and the statement has been explained to me to my satisfaction.
3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.
4. I give consent for the obtainment of medical records from Medicare Benefits Schedule, Pharmaceutical Benefits Scheme and hospital and emergency datasets which pertain to the costs involved in the health care of my child or relative(s) in this study. *Please sign the MBS and PBS Participant Consent form.* Agencies/data custodians providing Medicare Benefits Schedule, Pharmaceutical Benefits Scheme, hospital and emergency information will only be provided with identifying information (e.g. name, date of birth, address) in order to provide data pertaining to the costs and resources used in the health care of my baby in this study.
5. I understand that I can withdraw from the study at any time without prejudice to my relationship to the Hospital.
6. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.
7. I understand that if I have any questions relating to my participation in this research, I may contact Research team on (02) 9399 1817, who will be happy to answer them.
8. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the Research Ethics Secretariat, Research Ethics & Governance, The Royal Children's Hospital, Level 4, South Building, 50 Flemington Road, Parkville Vic 3052, Ph: 03 9345 5044

**Signature of participant**

**Please PRINT name**

**Date**

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**Signature of witness**

**Please PRINT name**

**Date**

\_\_\_\_\_

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**Signature of investigator**

**Please PRINT name**

**Date**

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Please return the completed consent form in the reply-paid envelope provided. A study research assistant will contact you to make arrangements convenient for you to administer the questionnaire. A copy of this form will be sent to you for your records (please tick one option).

Post copy of consent                       Email copy of consent

I would like to be contacted to consider any future extensions of this study or future research (please tick one option).

Yes     No



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### WITHDRAWAL OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the Hospital or my medical attendants.

I request that the study handles the information they have collected about my child and I in the following way (choose one option):

- DESTROY all information collected about my child/family member and I so it can no longer be used for research
- RETAIN all information collected about my child/family member and I so it can continue to be used for research

I understand that:

1. no further information about my child/family member and I will be collected for the study from the withdrawal date;
2. information about my child/family member and I that has already been analysed and/or included in a publication by the study, may not be able to be destroyed; and
3. choosing to withdraw my child/family member and I from the study will not affect my child/family member's access to Health Services or Government benefits.

**Signature of participant**

**Please PRINT name**

**Date**

\_\_\_\_\_

The section for Revocation of Consent should be forwarded to email [pregen@neura.edu.au](mailto:pregen@neura.edu.au).