



## The Follow-up Study: Participant Information Sheet

You are invited to take part in the Gomeri Gaaynggal Study. This study is being run by Associate Professor Kirsty Pringle from the University of Newcastle in partnership with the Gomeri Gaaynggal Advisory Committee, the Tamworth Aboriginal Medical Service (TAMS), and the Tamworth Local Aboriginal Land Council (TLALC).

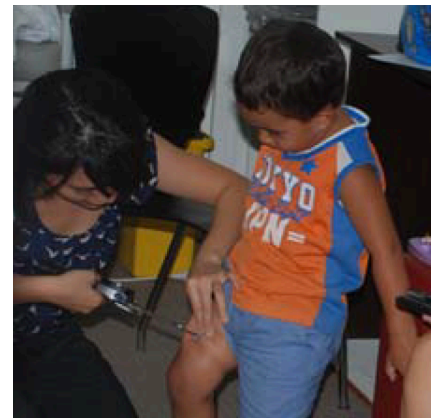
Before you decide if you want to take part in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with your family.

### **1. Why is this research being done?**

You have been helping us to understand how Australian Aboriginal and Torres Strait Islander babies grow and develop during pregnancy. Now we would like to understand more about how these babies grow and develop in childhood. We also want to understand more about how pregnancy affects mum's health later in life.

### **2. Who can be involved?**

Mothers and babies who have participated in our pregnancy study.



### **3. Are there any reasons why this study may not be suitable for me?**

If you are not planning to stay in the Tamworth area for the next year or two this study may not be right for you. Ideally, we would like families to be planning to stay in the area so we can contact you to see how you and your baby/child are going throughout the first 3 years of your child's life. If you are less than 16 years old, are highly dependent on medical care, have a mental impairment or intellectual disability or poor understanding of English this may not be suitable for you.

### **4. What happens if I join the follow-up study?**

If you agree to participate in this study, you will be asked to sign the Participant Consent Form for yourself and/or your child. One of our Aboriginal staff will be able to help you and answer any of your questions or concerns. You and/or your child do not have to take part in all parts of the study. Our consent forms are set up so that you can tick only the parts of the study you want you and your child to take part in.

If you choose to take part in the follow-up study, we will try and organise three visits in the first year of your child's life, then one per year for the next two years.

Surveys: We will ask you a few questions so that we can better understand what things effect your health and the health of your baby/child. These include:

For mums:

- The things you eat
- Your mental health
- Stressful life events and how these affect you
- Smoking
- Your general health and health history
- Your demographics (things like income, employment, and education).
- Your experiences with breastfeeding support

For babies:

- The things your child eats/drinks
- Your child's hearing and speech
- Your child's general health and health history

These surveys can be done in person with our Aboriginal staff when you attend the Tamworth Aboriginal Medical Services for your study appointment. They can also be done online at home if you prefer.

Body measurements:

For mums:

At each visit, we will measure your height and ask you to stand on a special scale (called an InBody machine) that measures what your body is made up of (for example: muscle, water, fat). We will also take some body measurements (like your weight and the size of your waist, arms, and legs) and your blood pressure.

For babies:

At each visit, we will measure how long or tall your baby is growing, how much weight they are gaining. We will also measure how much fat your baby is storing under the skin (this is called a skin-fold measurement) and your baby's blood pressure. None of these measures can hurt your baby.

Biological samples:

For mums:

We would like your permission to take samples of your:

- Blood (about 2 tablespoons or 30mL) at each study visit.
- Urine (about half a cup or 50mL) at each study visit.

We collect all of these samples so that we can measure the health of your kidneys and heart, hormones and markers of inflammation, chronic disease, nutrition, infection, and stress.

For babies:

We will ask to take a urine sample from your baby at each visit. We do this by putting a special pad in their nappy or using a collection jar during their visit.

We can use this sample to measure hormones and markers of inflammation, chronic disease, heart and kidney health, nutrition, and infection.



Medical records: Researchers need to find out about you and your child's medical health and health history. We will get this information from your medical records with your permission.

## 5. Study Timeline:

Study Visit	Surveys to complete*		Body measurements taken*		Biological samples taken		Time taken	Where
	Mum	Baby	Mum	Baby	Mum	Baby		
Visit 1 (1 month)	1	1	/	/	/	/	15 minutes	Online
Visit 2 (3 months)	7 6	3	Yes	Yes	Blood Urine	Urine	4 hours and 40 minutes*	TAMS
Visit 3 (6 months)	7 6	5	Yes	Yes	Blood Urine	Urine	4 hours and 40 minutes*	TAMS
Visit 4 (12 months)	6	5	Yes	Yes	Blood Urine	Urine	4 hours and 40 minutes*	TAMS
Visit 5 (2 years)	6	2	Yes	Yes	Blood Urine	Urine	4 hours and 40 minutes*	TAMS
Visit 6 (3 years)	6	2	Yes	Yes	Blood Urine	Urine	4 hours and 40 minutes*	TAMS

\* If you grant the study permission to access your medical records, the number of surveys and body measurements you may be asked to complete may be reduced. This is because we can get some of this information from your medical records. This should decrease the amount of time each visit takes. You will also be given the chance to do some of these surveys online at home before or after your study appointment.

### 5. What will happen to my samples?

Both your own and your child's samples will be tested and stored at the Hunter Medical Research Institute in Newcastle. Your/your child's samples can only be kept for a maximum of 5 years after the study end date.

### 6. What if I don't want to take part in this study, or want to withdraw later?

Participation in the study is your choice. Your health care will not change if you choose to take part in the study or not. You and/or your child can stop at any time, you do not have to give a reason. **You can ask to have all your/your child's data, blood and urine samples destroyed at any time.** An exception to this is in the case of an adverse event, or a serious adverse event, such as if one of our participants or staff were injured, where the information needs to be retained for regulatory reporting.

### 7. What are the risks of being in this study?

For some participants bruising, dizziness &/or fainting as a result of the mother's blood test. Some individuals may feel upset when discussing issues relating to breastfeeding experiences, body weight and/or when having their body measured. Participants may feel upset when asked about their mental health &/or stressful life events and how these affected them. Participants may experience some discomfort during the skin-fold test. These risks are minimised using qualified & experienced staff.

### 8. What are the benefits of being in this study?

***There is unlikely to be any benefit to individual participants over the benefits of routine health care.*** You will have the opportunity to have additional body measurements and tests to watch you and your baby's health during childhood. This can be discussed with the team who will help you to use this additional information in a beneficial way.

## 9. How will my identity be protected?

Any information you provide for this study will remain private & will be stored in a locked filing cabinet or password protected data file. Only the research team will have access to your information. All participants will have a study code so that you are not easily identifiable. Personal details that identify you, such as your name & address, will be removed when the study is complete. Personal information will be accessed, used and stored in accordance with the *Commonwealth Privacy Laws & the NSW Health Records & Information Privacy Act 2002 No 71*. According to the *Children and Young Persons (Care and Protection) Act 1998 (NSW) No 157*, the research team is required to report any information that tells them that children/young persons are at risk of harm.



## 10. How will I get informed about the results from the study

Once approved by community, the results will be presented in scientific journals and at conferences. Individual participants will not be identified in these presentations or publications. Posters showing the findings of the study will be available at the Tamworth Aboriginal Medical Service and Land Council. We will also present at community events and run programs with the Bumbira Arts and Culture team aimed at improving the health of mums and bubs.

**For all information about the study and our findings visit our website!**

[www.gomeroibabies.org.au](http://www.gomeroibabies.org.au)

## 11. Questions about this research

If you have any questions, you can contact the Gomeri Gaaynggal Study Team by:

**Email:** [ggstudy@newcastle.edu.au](mailto:ggstudy@newcastle.edu.au)

**Phone:** (02) 4042 0372

## 12. Complaints about this research

This research has been approved by the Hunter New England Human Research Ethics Committee, Reference No. 2021/ETH00488 and the Aboriginal Health and Medical Research Council Ethics Committee, Reference No. 1821/21.

Should you have concerns about your rights as a participant in this research, or you have a complaint about the way the research is conducted, it may be given to the researcher, or, if an independent person is preferred, please contact:

The Hunter New England Research Office:

**Address:** Level 3, POD, HMRI, Lot 1 Kookaburra Circuit, New Lambton Heights NSW 2305.

**Phone:** 02 4921 4140.

**Email:** [HNELHD-ResearchOffice@health.nsw.gov.au](mailto:HNELHD-ResearchOffice@health.nsw.gov.au)

Quote the reference number: 2021/ETH00488

Aboriginal Health & Medical Research Council  
Ethics Committee:

**Address:** 35 Harvey Street, Little Bay, NSW 2012

**Email:** [ethics@ahmrc.org.au](mailto:ethics@ahmrc.org.au)

and quote the reference number: 1821/21

## 13. The artist behind our logo



The Gomeri Gaaynggal Study logo titled 'Sacred Mother' was created by Aboriginal Artist Georgina Altona. It expresses the sacredness of woman and the gift of child. Georgina's message for us is that:

***"We are all Sacred Mothers."***