



**THE
ORIGINS
PROJECT**



**TELETHON
KIDS
INSTITUTE**
Discover. Prevent. Cure.



**Joondalup
Health Campus**
Part of Ramsay Health Care



A HEALTHY START
for a Better Future

PARTICIPANT INFORMATION BOOKLET

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WHAT IS THE ORIGINS PROJECT?

LOCAL RESEARCH. GLOBAL IMPACT. The ORIGINS Project is the largest study of its kind in Australia, following 10,000 families over the next decade to improve child and adult health. The unique long-term study is one of the most comprehensive studies of pregnant women and their families in Australia, recruiting families who are receiving pregnancy care or planning to deliver their baby at Joondalup Health Campus, as well as families from the Joondalup and Wanneroo communities. ORIGINS is a collaboration between the Telethon Kids Institute and Joondalup Health Campus.

PARTICIPATING IN ORIGINS

This participant information booklet will tell you all you need to know about being a participant in The ORIGINS Project.

DO I HAVE TO TAKE PART IN ORIGINS?

Participation in ORIGINS is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the Joondalup Health Campus.

WHAT IS THE AIM OF ORIGINS?

Chronic diseases like diabetes, allergies, eczema, heart disease, obesity and poor mental health are affecting more of our children than ever before. Research shows that life factors such as genetics, paternal health and a child's early environment – even while in the womb – can influence the risk of developing these chronic health conditions and diseases.

**The
Joondalup
Health
Campus
is located
in one of
the fastest
growing
areas in
Australia**

The aim of the ORIGINS project is to understand and overcome these modern health conditions, providing kids with a healthy start in life for a better future. With your participation, ORIGINS will create a Databank and a Biobank (see [pages 6-12](#)) that can support a diverse range of research intended to examine how early life factors can influence the health and development of the next generation of children from the first moments of life.

HOW MANY PARTICIPANTS?

10,000 families over a decade.

WHAT WOULD I NEED TO DO?

- 1 or 2 visits to the ORIGINS offices during pregnancy (depending on gestation)
- 3 follow-up assessments with your child until 5 years of age, including sample collections from you and your child
- Regular online questionnaires to complete
- Drop-off samples at various time points

Please refer to [pages 14 and 15](#)

WHO IS IT FOR?

Pregnant women and their partners who are receiving pregnancy care or delivering their baby at Joondalup Health Campus, and families from the Joondalup and Wanneroo communities are eligible to participate in ORIGINS.

WILL THERE BE A COST TO ME?

All visits, tests and medical care required as part of ORIGINS will be provided at no cost to you. In appreciation of your involvement in the Project, participants who complete online questionnaires and/or sample collection will go into a monthly draw to receive a \$100 Coles Myer voucher. All participants also receive a \$20 Coles Myer voucher as a thank you for completing the antenatal questionnaires.



AFTER THE BIRTH OF YOUR CHILD

We offer extra paediatric clinic visits (at no cost to participants) including:

- developmental assessments
- monitoring of growth and body composition
- allergy and immune testing

WHAT DOES MY PARTICIPATION INVOLVE?

Where possible, ORIGINS visits will coincide with your routine clinic visits as part of your regular antenatal and baby care. Please see [pages 14 and 15](#) for more details about the data and biological sample collection time points.

- During your pregnancy, we will ask you questions about your health and well-being, diet, physical activity, and your environment. Many of these questions are already part of routine care, but we will ask about these in more detail.
- During your hospital clinic visits you will provide samples (such as blood and urine) which are collected as part of your routine care. ORIGINS has been given permission to access these routinely collected samples. We will also collect additional samples (such as saliva, stool and breast milk), as part of a separate ORIGINS appointment. Some of these samples you will be asked to collect yourself at home. The purpose of this is explained in the Biobank section of this booklet (see [page 6](#)).
- After the birth of your child, you will be invited to attend appointments (approximately 60-90 minutes each) when your child is 1, 3 and 5 years of age, so that we can monitor your child's growth, health and development.
- Some questions will also relate to your partner and/or your child's biological father.
- We will ask for your permission to contact other health professionals and health services to release your child's health information to us. We would like to access your child's routinely collected information. For example, information relating to your child's routine tests, growth, and development. By providing us with permission to contact the health professionals you have seen, we will be able to gain a fuller understanding of your child's health.



HOW WILL MY FAMILY'S HEALTH AND DEVELOPMENT BE FOLLOWED?

Before you and your baby leave hospital, an ORIGINS staff member will talk to you about enrolling your baby into ORIGINS.

We will follow your child's progress through both ORIGINS Kids Checks at 1 year, 3 years and 5 years of age, as well as regular online questionnaires (see details of timing on [pages 14 and 15](#)). There will be questions about your child's developmental progress and milestones, history of symptoms and illnesses. If there are any abnormal indicators on testing, your child will be referred to an appropriate clinician.

These are some of the assessments that will occur:



PEA POD and BOD POD: Before your baby goes home from hospital, a research assistant will use a scale called a PEA POD to measure your baby's body composition. Whilst your baby is asleep on the scale, it measures body fat using air displacement. At three and five years of age, your child will have this measurement taken again in a larger BOD POD.

Allergies: At the ORIGINS Kids Checks, your child will have an allergy skin prick test to determine whether s/he has a reaction to common allergens such as foods, cats, dust mites or pollen. If there are any positive allergy tests, your child may be referred for follow-up. Allergic diseases (such as food allergies, eczema and asthma) are now extremely common, affecting around 25% of Australian children – the allergy skin prick test is an important early measure of the effects of the modern environment on immune health.

Body size measurements: At the ORIGINS clinic visits, we will take body size measurements such as weight, height and arm circumference.

Veggie meter: ORIGINS uses a non-invasive veggie meter to measure fruit and vegetable intake by recording the level of carotenoid pigments in a person's skin.

Skin barrier function: Shortly after birth, the team will use a non-invasive instrument to assess the barrier function of yours, your partner's and your baby's skin. This measurement is a good indicator of the integrity of the skin barrier function (i.e. its ability to retain moisture) and can be used as an indicator of skin irritation and for the analysis of irritancy potential or protective properties.

WHAT ARE THE BENEFITS TO MY FAMILY?

Each child will receive free allergy, growth and developmental assessments at 1 and 3 years of age and a general assessment at 5 years of age. If an issue is identified, a referral to the appropriate services and follow-up information will be provided to parents. The ORIGINS paediatrician does not provide ongoing management but identifies and refers appropriately.

Please note: Though these assessments will provide you with accurate and useful information about your child's health and development, they are not a substitute for professional advice from your child health nurse and family GP. All sample collections are also optional.

Being involved in ORIGINS will give you the opportunity to help improve the health of our next generation.



WHAT ARE THE POSSIBLE RISKS OF TAKING PART IN ORIGINS?

Medical procedures and sample collections sometimes cause minor side effects. You may have none or some side effects. Having a blood sample taken may cause some discomfort, bruising or bleeding. If this happens, it can be easily treated.

At 1, 3 and 5 years of age, your child will have an allergy skin prick test. In this test, a liquid containing tiny amounts of allergens is placed on your child's arm or back and a small prick is made on the skin. If your child has an allergic response a small bump (or wheal) will develop. This may cause some temporary discomfort such as itching but should subside within 2 hours.

LEVELS OF COMMITMENT

There are three possible levels of participation in The ORIGINS Project. You will be asked to sign a consent form for yourself and your child for the level that you choose. Partners are also strongly encouraged to join.

Level 1: Full participation (please read [pages 14 and 15](#))

This is the level that most benefits you and the project, but requires a greater time commitment.

There will be online questionnaires for you to complete and biological samples to provide. You will receive reminders to complete the questionnaires or drop off samples. Free ORIGINS *Kids Checks* at 1, 3 and 5 years of age will be included and you will have the opportunity to participate in additional sub-projects - smaller nested interventional studies that focus on specific areas of child health and development.

ORIGINS will access the collection of your routine data (see [page 11](#)).

We will conduct data linkage of collections held by the Australian Government, such as prescription medications dispensed by pharmacies and childhood immunisation records.

We will seek permission to contact private and government health services (e.g., the Government of Western Australia Child and Adolescent Health Service) to release routine information relating to your child's health for the purposes of The ORIGINS Project.

Level 2: Collection of your routine data and routine biological samples

If you would like to contribute, but are unable to commit yourself and your child to the whole project, we invite you to allow us to collect data about you and your child from your records at the Joondalup Health Campus and through data linkage to collections held by the Australian Government, such as prescription medicines dispensed by pharmacies and childhood immunisation records. We would also invite you to allow us to access the remainder of any routine biological samples you have collected, such as placental tissue and blood samples and ask your permission to contact private and government health services as above.

Level 3: Data Linkage to collections held by the Australian Government

If you are unable to participate in either of the above, we are still able to gain valuable information for research purposes if you agree to let us use data linkage to access your records held by the Australian Government, such as prescription medicines dispensed by pharmacies and childhood immunisation records.



WHAT IS A BIOBANK?

A Biobank is a collection of human biological samples, and any biological and genetic data that is generated from the samples, to be used for research purposes. The ORIGINS biological samples collected (such as blood, urine, stool, cheek swabs and breast milk) will be used to investigate early life origins of health and disease.

Research involving human genetic information analysed in conjunction with other personal or health data has become increasingly important for understanding risk factors underlying complex diseases.

Such research is critical to improvements in detection, prevention, diagnosis, treatment and cures. To support this research, great emphasis has been placed on the establishment of resources comprised of data, biological samples and information derived from the analysis of those samples.

The Telethon Kids Institute, internationally recognised for research excellence in maternal and child health, is the custodian of the ORIGINS Biobank and is responsible for its management. If The ORIGINS Project ceases, the Biobank will remain with the Institute to ensure the Biobank continues to be available for researchers.



WHERE WILL THE BIOBANK BE STORED?

The ORIGINS Biobank sponsor is Western Diagnostic Pathology (WDP), the pathology company based at the Joondalup Health Campus. WDP staff process most of the ORIGINS biological samples at the WDP state laboratory. WDP is a comprehensive medical laboratory and pathology practice with over 10 laboratories and 140 collection centres located in metropolitan Perth, regional Western Australia and the Northern Territory. You will be able to drop off your samples at nominated WDP collection centres. The remainder of the biological samples are processed at the Telethon Kids Institute within the Perth Children's Hospital. The ORIGINS Biobank will be stored long-term at this site, as well as on the premises of a Telethon Kids Institute subsite in Subiaco.

DID YOU KNOW?

**25% of kids
have asthma**

WHAT SAMPLES ARE BEING COLLECTED, AND WHY?

All of your samples will be stored with a unique ID number. The ID number is known only to a small group of researchers in ORIGINS, so only they can identify the person from whom the sample came.

These are the samples that are collected:

Blood: can be used to monitor metabolism, immune function and obtain DNA.

Breast milk: contains important nutrients and immune factors and can be used to study how these are influenced by the early environment.

Cord blood: cord blood analysis can measure patterns of metabolism (chemical changes that occur in the body) and immune function (how the immune system works) in your baby before birth. It will help to determine how these are influenced by the environment in pregnancy.

Guthrie test: a routine neonatal screening, performed on all infants within a few days of birth to test for serious genetic conditions. A nurse or midwife pricks the infant's heel and collects a few drops of blood with an absorbent Guthrie card for testing and storage.

For ORIGINS participants, the nurse or midwife will collect blood on a second Guthrie card

(ORIGINS Research Guthrie Card) immediately after the initial test, for research purposes. No additional blood will be drawn.

Hair: can be used to measure stress and other hormone levels.

House dust samples: (vacuumed from the floor of your house) can be used to measure allergen levels, such as house dust mites, as well as levels of environmental contaminants, and bacterial products, which might influence the developing immune system.

Placenta and umbilical cord tissue: Umbilical cord and placental tissues, which are normally discarded, provide an opportunity for painless tissue sampling. They can be used to measure the activity of genes that might be altered by the early environment.

Stool and meconium (first stool): can be used to examine the presence and types of bacteria in a person's gut. There is growing evidence that the patterns of 'friendly bacteria' in our gut have a strong influence on our health.

Saliva and cheek swabs: can be used to measure levels of antibodies, stress hormones, bacteria and to obtain DNA.

Urine: can be used to measure products of metabolism. Even the healthy chemical products of friendly bacteria, living in our gut, can be looked at in our urine.

Baby teeth: Baby teeth tell stories of a child's general health. ORIGINS would like to collect and analyse one tooth from your infant, when it naturally falls out or if it is extracted by a dentist.

Amniotic fluid: If you have a caesarean section, the fluid will be collected and stored. Amniotic fluid provides the best measure of the intrauterine hormone environment, which has previously been linked to differences in behavioural and cognitive development.



DNA AND GENETIC TESTING

Please read this section and the brochure about DNA before agreeing to participate in ORIGINS – if you decide not to provide samples for obtaining DNA, you can still participate in all other parts of ORIGINS.

With your consent we will store samples of your blood, saliva and cheek swabs that may be used for future DNA (genetic) testing. This testing measures how genes interact with diet and environmental exposures to influence the development of many organ systems and the risk of chronic health problems. Examples include allergies, asthma, autism and other developmental disorders, obesity and diabetes.

DNA storage

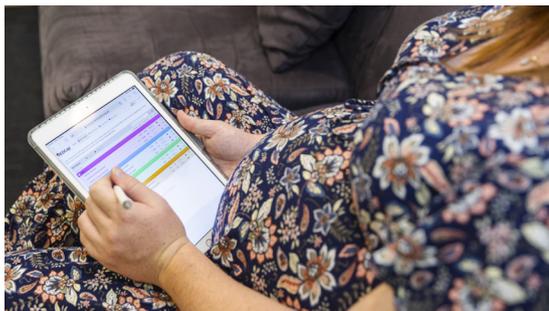
You will always have the right to ask us to destroy your samples. If you would like your DNA or other biological samples destroyed, you may contact The ORIGINS Project researchers (contact details on the back of this booklet). [The ORIGINS website](#) provides further information related to withdrawal.

The researchers' commitment to you

Our understanding of genes and DNA testing is changing very quickly. The researchers who will be using the samples stored in the ORIGINS Biobank will aim to protect your interests at all times. The research will be carried out according to the consent form that you sign. Your samples will be stored very carefully, but a guarantee cannot be given against accidental damage or loss of the samples beyond the control of the ORIGINS research team.

While the DNA samples may be used for a number of other tests in the future, further research in this area using your samples will only be done with the approval of the Ramsay Health Care WA|SA Human Research Ethics Committee (RHC WA|SA HREC).





WHAT IS STORED IN THE ORIGINS DATABANK AND WHY?

Data are pieces of information. By signing the ORIGINS consent form you agree to the following records of your or your child's data being stored in the ORIGINS Databank for future use by researchers:

- **Digital questionnaires** completed early in your pregnancy, relating to your and your partner's medical history, including allergies
- **Online questionnaires** including topics such as sleep, exercise, diet and your environment
- **Ages and Stages questionnaire**, an internationally recognised developmental assessment, online
- **Australian Eating Survey**, an Australian validated food frequency questionnaire, online
- **Conners Early Childhood**, a comprehensive questionnaire that assesses behaviour and emotional and social development in pre-school children, online
- Your **health records** stored at the Joondalup Health Campus (this includes your weight, height, blood pressure measurements, medications prescribed)
- Your routinely collected information that has been provided to ORIGINS by **other private and government-operated health and allied services** (e.g. immunisation records, GP records, hospital admissions in WA, assessments completed as part of other services such as on your child's growth and development)
- **Education and community data** from the WA Government (e.g. NAPLAN results, Australian Early Development Census, and information in the Purple Book)
- Information derived from the **analyses of your Biobank samples** (as approved by RHC WA | SA HREC)
- **Ultrasound images and reports** including measurements from the routine anatomy scan performed at 18 weeks of pregnancy
- **Pathology reports** include your blood test results such as the Glucose Tolerance Test which is a routine test performed at 28 weeks of pregnancy
- Information derived from your **ORIGINS appointments** and involvement in **ORIGINS sub-projects**

WHERE WILL THE DATABANK BE STORED?

Data collected will be stored on secure servers at the Telethon Kids Institute. The servers are in a secure building and access is restricted to a few named individuals. Other data are stored in locked offices, filing cabinets, and on password-protected computers at the Telethon Kids Institute. Access to the building is via an electronic tag and individual rooms are kept locked when unoccupied.

Using a unique ID, your personal data will be de-identified and stored separately from your administrative data (identified data) containing your contact details. To enable data linkage with your records held by the Australian Government, such as the Child and Adolescent Health Services, we will share demographic information (e.g. name, date of birth). Your identifiable data is accessible only to specified members of the data management team.

EXTERNAL DATA STORAGE

The ORIGINS Project utilises a number of external service providers and applications to assist in the collection of specific research data (e.g. Ages & Stages Questionnaires) and for administrative purposes (e.g. YAROOMS for room bookings). The data on external servers are stored in secured environments and managed by a specialized and trained personnel with appropriate level of stewardship to handle the data according to the WA and Australian data privacy laws.

DID YOU KNOW?

**One in four
Australian children
are overweight or
obese**



CONFIDENTIALITY

The ORIGINS team is committed to protecting the confidentiality and privacy of data and biological samples. All members of the ORIGINS team are required to sign confidentiality agreements.

Researchers, collaborators and partners will need to apply for approval from RHC WA|SA HREC in order to access the ORIGINS Biobank and Databank. Your data and biological samples will not be sold, however, researchers, collaborators and partners, may be charged a fee to recover some of the costs of collecting the information stored in the ORIGINS Databank and Biobank. The ORIGINS Project collaborates with a number of overseas researchers and partners. In some cases, these collaborators have unique expertise in analysing and testing samples, expertise that is not available in Australia. As a result, your data or biological samples may be sent overseas for research. All transfers of data or biological samples will be approved by the RHC WA|SA HREC, and where required may also be overseen by an equivalent ethical approval body overseas. When data and/or samples are released to researchers, collaborators or partners, no identifying information will be provided.

The results from research based upon the ORIGINS Databank and Biobank may eventually be published in medical journals or at professional meetings, but you and your child will not be identified in any way. In very rare circumstances, disclosure of your health information will be required by law, for example, as a result of a court order.

KEEPING IN TOUCH

The ORIGINS website is a great way to keep up to date with the latest ORIGINS news. We will also send emails to remind you to complete questionnaires and to drop off your biological samples.

Check out our website for the latest news about ORIGINS:

ORIGINSproject.telethonkids.org.au

With your consent, you may be contacted to participate in future research studies related to ORIGINS.

WITHDRAWAL

Should you choose to withdraw, the information and samples that you have provided will continue to be kept securely and used for ORIGINS related research projects unless you request for them to be destroyed. Your signed consent and withdrawal forms will be kept as a record of your wishes. Such a withdrawal would prevent information about you from contributing to further analyses, but it would not be possible to remove your data from analyses that had already been done. Please visit the ORIGINS website for further information about the withdrawal options.

WHAT WILL HAPPEN DURING THE PROJECT AND WHEN?

ANTENATAL ENROLMENT VISIT

At 20, 28 or 36 weeks of pregnancy

60 minute appointment at Joondalup Health Campus

Online questionnaires from home

You will be **introduced** to ORIGINS and shown how to access the online questionnaires about your **health, diet, lifestyle, and environment**.

A sample of your, and your partner's (if possible), **blood, hair, urine** and **saliva** will be collected and a **cheek cell swab** will be taken.

We will also ask you to bring in a small sample of **stool** from home.

If you have any **ultrasounds**, the reports will be included.

We will use a **Veggie Meter** to measure an indication of your **fruit and vegetable intake**.

ANTENATAL FOLLOW-UP APPOINTMENT

36 weeks of pregnancy

60 minute appointment at Joondalup Health Campus

Online questionnaires from home

We will remind you to complete the online questionnaires.

A sample of your **blood** and **hair** will be collected.

Your **partner** (if possible) will also be asked to provide these samples if they have not already done so previously.

Ideally, partner's **blood pressure** and **height** and **weight** will also be measured.

We will use a Veggie Meter to measure your **fruit and vegetable intake** (if not done previously).

We will also ask you to bring in a small sample of **stool, urine, saliva** and a **cheek cell swab** from home.

Prior to the 36 weeks visit you may be asked to collect a small sample of **dust** from your home.

AT DELIVERY AND BEFORE YOU GO HOME

Collections should take around 20-30 minutes

Joondalup Health Campus

At delivery, **cord blood, amniotic fluid** and **placental tissue** will be collected. (note: this is optional)

We will collect information about the delivery of your baby and details including **name, sex, birth weight, length, and head circumference**.

A non-invasive measurement will also be taken to assess the effectiveness of your, your partner's and your baby's **skin barrier function**.

Before you go home, a small sample of **colostrum**, (first breast milk) will be collected.

Your baby will have a sample of **meconium** (first stool) collected and a drop of your baby's heel blood, for an **ORIGINS Research Guthrie Card**, will be collected.

Your baby's **body fat composition** will be measured in the **PEA POD**.

2, 4, 6 & 9 MONTHS OF AGE

Home samples at 2 & 6 mths

Online questionnaires at 4 & 9 mths

We will remind you to complete the online questionnaire for each time point. These will include questions about your child's **communication, motor** and **social/emotional skills** and **developmental milestones**.

At two and six months we will remind you to collect some home samples of you and your baby's **stool, urine** and **breast milk** if you are breast feeding.

1½, 2, 3½ & 4 YEARS OF AGE

Online questionnaires from home

We will remind you to complete the online questionnaires for these time points.

As they get older, if your child loses a tooth, naturally or due to dentist extraction, we would appreciate collecting it to assess dental and general health.

1, 3 & 5 YEARS OF AGE

90-min *Kids Check* appointment, including allergy testing & sample collection

Online questionnaires

The online questionnaires will include an assessment of your child's **diet, health, environment** and **development**.

Your child will have a **developmental check** and your child's **ears** will be checked and **weight, height** and **head circumference** will be measured.

Your child will have an **allergy skin prick test** and be examined for signs of **allergic disease**.

You will be asked to collect a small sample of **dust** from your home, as well as a **stool, saliva and urine** sample from your child, as well as a **cheek cell swab**.

A small sample of your, your partner's and child's **blood** and **hair** will be collected.

If you are still **breastfeeding** you will be asked to provide a sample of breast milk.

Blood pressure will be measured for you, your partner and older child, if possible.

If your child has been hospitalised, we may need to access your child's medical records to document the reasons for hospitalisation and the treatments given.

Around the three-year and five-year timepoints, you will also be asked to attend a 30-min **BOD POD** assessment measuring the **body composition** of your child.

WHO ARE THE RESEARCHERS LEADING ORIGINS?

The ORIGINS Project is led by:



Professor Susan Prescott

Paediatrician and Allergy Specialist
Perth Children's Hospital
Telethon Kids Institute
University of Western Australia



Professor Desiree Silva

Paediatrician
Joondalup Health Campus
Telethon Kids Institute
University of Western Australia

ANY QUESTIONS?

If at any time during ORIGINS you have any questions:



(08) 9408 3118



ORIGINSproject@telethonkids.org.au



ORIGINSproject.telethonkids.org.au

ANY CONCERNS?

The ethical aspects of this study have been approved by the Ramsay Health Care WA|SA Human Research Ethics Committee. If you have any complaints or reservations about any ethical aspect of your participation in a research project, please contact the Consumer Liaison Office at Joondalup Health Campus on (08) 9400 9404 who will direct your complaint to the most appropriate person. Any complaint you make will be investigated by an independent party, treated in confidence, and you will be informed of the outcome.

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The ORIGINS Project is generously funded by the Paul Ramsay Foundation and the Commonwealth Government of Australia through the Channel 7 Telethon Trust