

**THE  
ORIGINS  
PROJECT**



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



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



# THE AERIAL STUDY

(AIRWAY EPITHELIUM RESPIRATORY  
ILLNESSES AND ALLERGY)

**PARTICIPANT  
INFORMATION BROCHURE**



## What is the AERIAL study?

The Airway Epithelial Research Group from Telethon Kids Institute is interested in the possible contributors to childhood lung diseases such as asthma. The AERIAL study will specifically look at the cells lining the airways (epithelial cells) in the nose and lower airway at birth to help to understand the development of early-life airway conditions.

AERIAL is a sub-project of [The ORIGINS Project](#).

## Why is it important?

Airway epithelial cells act as a barrier to protect our lungs from toxins that we breathe in. They work continuously to keep the protective barrier tight, strong and efficient.

Our research shows that epithelial cells in children with asthma do not form a tight, strong barrier and have a different response to virus infections. We also know that viral infections in the first few months of life play an important part in the development of early-life lung conditions such as wheeze and allergy.

We have identified gene signatures for response to virus and barrier function in both lower airways and in the nose. The AERIAL study is looking to find out more about all these factors in the development of childhood lung disease.

## We will try and answer the following;

- Are we born with certain airway epithelial gene signature patterns?
- Are these gene signature patterns consistent in epithelial cells found in the placenta?
- Can exposures during pregnancy leave a fingerprint on the genetic material of the epithelial cells?
- How does the type and number of viral infections in first few months of life relate to the gene pattern and profiles identified?
- Are these gene signature patterns associated with the development of wheeze, allergy and asthma later in childhood?

## Who can participate in this study?

Any family participating in The ORIGINS Project can choose for their baby to be part of this study. Babies must be born after 32 weeks pregnancy and have no health concerns.

Families must have access to a mobile phone or equivalent device that can support the AERIAL Temperature Tracker app.

## What does participation involve?

If you choose to participate in the AERIAL study, there will be some requirements that are additional to the appointments and sample collections your involvement in the ORIGINS Project entails (detailed in the ORIGINS participant information booklet). Some AERIAL study information will be collected during your standard ORIGINS appointments, but there will also be additional participation activities.

**NB:** During COVID, we will be following the guidelines and recommendations of the WA Public Health Department and this may impact how we are required to take the nose swab and report the results of the virus test.

### Participation in the study includes:

- **ORIGINS - 20-weeks gestation:** Initial screening questionnaire by phone. AERIAL Participant Information Brochure sent by email.



▶ **ORIGINS - 36-weeks gestation:** You will complete an e-consent to join the study and receive a detailed explanation of the AERIAL Study and forehead thermometer.

▶ **AERIAL – follow up phone or video call:**

- An AERIAL team member will demonstrate how to download and use the AERIAL mobile app and the forehead thermometer, which will help to keep a record of your baby's daily temperature and signs of viral infections.

▶ **ORIGINS – birth:** If you have consented your placenta to The ORIGINS Project, a small section of the protective sac (amnion) will be sampled for the AERIAL Study.

▶ **ORIGINS – soon after birth, in hospital:**

- a trained member of the study team will use a very small brush to take a sample of cells from inside your baby's nose. This will take about 2 seconds for each nostril. If we miss you in hospital, we will arrange for a study nurse to visit you at home to collect this sample.

▶ **AERIAL - At home after birth to 1 year.** The following activities are to be carried out by you:

● **DAILY**

You will be prompted by the AERIAL app to record your baby's temperature, using the app, and to note any relevant symptoms e.g. runny nose, cough

If the temperature recorded is high with relevant symptoms, you will be contacted by the AERIAL team for follow up testing for respiratory viruses for your baby.

● **EVERY 3 MONTHS - Background Virus Check**

You will be prompted by SMS reminder to complete a short symptom chart for your baby, using a link to an online questionnaire.

Someone from the AERIAL team will contact you to organise a nose swab from your baby for virus identification.

▶ **ORIGINS – follow up nose samples will be taken at the ORIGINS one- and/or three-year scheduled visits.**

We will use a very small brush to take a sample of cells from inside of your child's nose. This will take about 2 seconds for each nostril.

## What are the risks of taking part in this study?

There are no long-term side effects for your baby from having nose samplings taken. Though your baby may feel some discomfort, and may cry, it will be very much like their reaction to the Guthrie (heel prick) test they have at birth.

During a pilot study, 20 newborn nose samplings were observed and only one baby cried, five babies sneezed, and 14 babies did not react at all.

## What are the possible benefits of taking part?

You will have real-time information recorded on the AERIAL app, which you can take to your GP if you have any concerns about your baby's health.

If your baby has follow-up nose swabs, you will receive the results from the respiratory virus testing.

Your participation in this study will contribute to research that could change the way we identify and treat early-life airway conditions, such as asthma, wheeze and allergy.



## What will happen to my information and samples collected in this study?

All information gathered about you and your baby, such as personal and health details, AERIAL app temperatures and symptoms, and questionnaire answers will be treated with confidence.

No information that could identify either you or your baby will be released to any person not associated directly with the study.

Any genetic material or samples remaining after this study is completed will be stored according to the ORIGINS Biobank Guidelines and will only be used in future studies which have received ethical approval from the Joondalup Health Campus Human Research Ethics Committee.

You can contact the study team at any time and request that your baby's genetic material and samples be destroyed.

The results from the study may be published in medical journals, at professional meetings and in the media, but you and your baby will not be identified in any way.

## Can I withdraw from the study?

Participation in any research study 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 from this study at any stage. If you do decide to withdraw from this study, please note that:

- ▶ The information and samples that you have provided will continue to be kept securely and used for this study unless you request for them to be disposed of.
- ▶ You and your child will still be participants of The ORIGINS Project.

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

## Who are the researchers leading this study?

The lead Investigators are Professors Stephen Stick, Susan Prescott and Desiree Silva from the Telethon Kids Institute and the Joondalup Health Campus. Co-investigators of this study include research members of the WA Epithelial Research Program, and researchers based at the Telethon Kids Institute and The University of Western Australia.

## Ethical information

The ethical aspects of this study have been approved by 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 Joondalup Health Campus Executive Office on (08) 9400 9404. Any complaint you make will be investigated by an independent party, treated in confidence, and you will be informed of the outcome.

## Any Questions?

If you would like any more information about this study, please do not hesitate to contact the research study team at [aerial@telethonkids.org.au](mailto:aerial@telethonkids.org.au). Further information can also be found on our website: [originsproject.telethonkids.org.au/sub-projects/AERIAL](https://originsproject.telethonkids.org.au/sub-projects/AERIAL)

