



*Exhaled breath condensate from healthy infants*

**PARTICIPANT INFORMATION STATEMENT**

<b>HREC Project Number:</b>	<i>HRE2018-0407</i>
<b>Project Title:</b>	<i>Exhaled breath condensate from healthy infants</i>
<b>Principal Investigator:</b>	<i>Professor Graham Hall, Curtin University</i>
<b>Student researcher:</b>	<i>Ms Rhea Urs</i>
<b>Version Number:</b>	<i>1</i>
<b>Version Date:</b>	<i>24/04/2018</i>

**What is the Project About?**

Babies who are born very preterm often develop chronic lung disease. Researchers would like to know more about what causes this chronic lung disease and how to treat it. One way we can know more about what is happening in the lungs is to measure the air the babies breathe out. When the babies breathe into a cold tube, the air condenses into droplets which we can collect and analyse for different molecules. We call the condensed air 'exhaled breath condensate'. We have collected exhaled breath condensate samples from preterm babies. However, we do not have any exhaled breath condensate samples from healthy babies to compare them to. If we know the differences between the lungs of healthy babies and preterm babies, we can help find the best treatment for their lung disease.

Our project aims to collect and measure exhaled breath condensate from healthy babies. We will compare these to samples from preterm babies. This way, we can identify which molecules in exhaled breath condensate predict lung disease in babies who were born preterm. In future, this will help researchers find the best treatment for preterm babies with chronic lung disease.

We aim to collect exhaled breath condensate samples from 25 healthy babies, aged between 12 and 16 months old.

**Who is doing the Research?**

This project is being conducted by researchers at Curtin University, Telethon Kids Institute and Edith Cowan University. The results of this research project will be used by a student researcher, Rhea Urs, to obtain a Doctor of Philosophy at Curtin University and is funded by the University. There will be no costs to you and you will not be paid for participating in this project.

**Why am I being asked to take part and what will I have to do?**

We are asking parents of babies who were born at term (37 weeks gestation or more) if they are willing for their babies to take part in this research.

This research will involve your baby breathing normally through a mask into a cold tube for about 20 minutes, while they are asleep during their normal nap time. The exhaled air that your baby breathes out will condense into droplets in the cold tube, which we will collect and measure at a laboratory. We will then compare these results to our results from preterm babies.

We will also ask you a few questions about your baby's general health and if they have had any breathing problems. This questionnaire should take about 5 minutes to complete.



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The study will take place at a mutually convenient location, at a time when your baby is napping. If your baby attends a local daycare or play group, then researchers can come and collect exhaled breath condensate from your baby during their naptime, with your permission. Alternatively, you and your baby can visit the Telethon Kids Institute for the study. We will provide free parking for you at the Telethon Kids Institute. If your baby is asleep, this visit should take no longer than 30 minutes.

Optional Future Research: We would like you to consider allowing us to send you information about future research projects. Once you receive the information it is your choice if you decide to take part or not.

### **Are there any benefits' to being in the research project?**

There is no direct benefit to your child from participating in this research.

We hope the results of this research will allow us to better understand chronic lung disease in babies who are born preterm, and help to develop targeted treatments.

### **Are there any risks, side-effects, discomforts or inconveniences from being in the research project?**

There are no foreseeable risks from this research project. When collecting exhaled breath condensate, babies need to breathe normally through a mask into a cold tube. We will wait for your baby to be asleep and in a comfortable position before collecting exhaled breath condensate so that they are relaxed and can breathe normally during the collection. We have collected exhaled breath condensate in very preterm babies without any adverse events.

Apart from giving up your time, we do not expect that there will be any risks or inconveniences associated with taking part in this study. If you prefer to visit the Telethon Kids Institute for the study, then we will provide you with free parking at the Telethon Kids Institute.

### **Who will have access to my information?**

The information collected in this research will be re-identifiable (coded). This means that we will collect data that can identify your child, but will then remove identifying information on any data or sample and replace it with a code when we analyse the data. Only the research team have access to the code to match your child's name if it is necessary to do so. Any information we collect will be treated as confidential and used only in this project unless otherwise specified. The following people will have access to the information we collect in this research: the research team and, in the event of an audit or investigation, staff from the Curtin University Office of Research and Development.

Electronic data will be password-protected and hard copy data will be in locked storage. Samples will be securely transported to the laboratory at Edith Cowan University where they will be analysed. The information we collect in this study will be kept under secure conditions at the Telethon Kids Institute for 7 years after the research is published and then it will be kept indefinitely.

You have the right to access, and request correction of, your information in accordance with relevant privacy laws. The results of this research may be presented at conferences or published in professional journals. Your child will not be identified in any results that are published or presented.



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### **Will you tell me the results of the research?**

A summary of the project's overall results should be sent to participants at the end of the research (in about 7 months) and let you know the results of the research. Results will not be individual but based on all the information we collect and review as part of the research.

### **Do I have to take part in the research project?**

Taking part in a research project is voluntary. It is your choice for your child to take part or not. You do not have to agree if you do not want to. If you decide that your child can take part and then change your mind, that is okay, you can withdraw your child from the project. You do not have to give us a reason; just tell us that you want to stop. Please let us know you want to stop so we can make sure you are aware of any thing that needs to be done so your child can withdraw safely. If you choose for your child not to take part or start and then stop the study, it will not affect you or your child's relationship with the Universities or the Telethon Kids Institute. If you choose for your child to leave the study we will use any information collected unless you tell us not to.

### **What happens next and who can I contact about the research?**

If you would like any more information about the study, please do not hesitate to contact one of the research team. They are very happy to answer your questions.

<b>Name</b>	<b>Contact Number</b>
Ms Rhea Urs	08 9489 7819
Dr Shannon Simpson	08 9489 7794
Prof Graham Hall	08 9489 7816

If you decide your child can take part in this research we will ask you to sign the consent form. By signing it is telling us that you understand what you have read and what has been discussed. Signing the consent indicates that you agree for your child to be in the research project and have your child's health information used as described. Please take your time and ask any questions you have before you decide what to do. You will be given a copy of this information and the consent form to keep.

### **Who to contact if you have any concerns about the organisation or running of the study:**

Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number HRE2018-0407). Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email [hrec@curtin.edu.au](mailto:hrec@curtin.edu.au).