

### HOW IS MY PRIVACY PROTECTED?

All information we collect on you during the course of this research is kept strictly confidential and any information about you which leaves Telethon Kids will have your name and address removed so you cannot be identified.

### WHAT WILL HAPPEN IF I CHANGE MY MIND?

Don't worry, participation is completely voluntary, and you can withdraw at any time. Withdrawal from this study will not affect your relationship with ORIGINS, the researchers or organizations involved. If you withdraw information collected on you may still be used. Please contact Dr David Martino david.martino@telethonkids.org.au should you wish to withdraw.

### WHAT WILL HAPPEN WITH THE RESULTS OF THIS RESEARCH?

The findings from this study will be published in an academic medical journal and may appear in the media. We will keep you informed of the progress and results of the study through newsletters. You will not be identified in any publication.

### WHAT ARE THE RISKS AND BENEFITS OF PARTICIPATING?

There is very little risk in this study. By participating, you will receive an industry certified bench-top water filter that you can keep at the conclusion of the trial. You will receive a personalized report about the friendly bacteria in your child's tummy and you will be helping to ensure a healthy water supply for all Australians. Clean, safe water is a basic right for all human beings.

### FURTHER INFORMATION AND CONTACT DETAILS

The ethical aspects of this study have been approved by Joondalup Health Campus Human Research Ethics Committee. If you have any complaints or reservations about any ethical aspect of your participation in a research project, please contact JHC 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.



# TUMS

Supporting healthy tums in bubs

## PARENT/GUARDIAN INFORMATION BOOKLET

We are inviting you to consider taking part in this research study

- Before you decide whether to take part, it's 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. Discuss with friends and relatives if you wish.
- You are free to decide whether or not to take part in this study.
- Ask us if there is anything that is unclear or if you would like more information.





## WHAT IS TUMS ABOUT?

TUMS is a study looking at domestic tap water quality and the friendly bacteria that live in the gut (the microbiome).

Friendly gut bacteria perform essential duties related to digestion and play a vital role in our overall health. Children in particular need an optimal chance to develop a diverse range of healthy gut bacteria in the first few years of life.

Tap water is treated with disinfectants to ensure it's safe and free of harmful bacteria. This study aims to ensure that the way we treat tap water is also optimal for promoting a healthy tum in early childhood.

## WHO IS PARTICIPATING IN THIS RESEARCH?

Healthy term babies, who are part of the ORIGINS study are invited to participate when their baby turns six months, which is why you have been provided with information about this study. We are aiming to involve 200 families in this study from around WA.

## WHO IS LEADING THIS RESEARCH?

This study is funded by the Telethon Kids Institute and involves the ORIGINS investigators Prod Susan Prescott and Prof Desiree Silva, Dr Claus Christopherson, Dr Debbie Palmer, the Water Corporation and the State Department of Health. The lead investigator on the trial and the primary contact if you have any question is Dr David Martino.

David.Martino@telethonkids.org.au  
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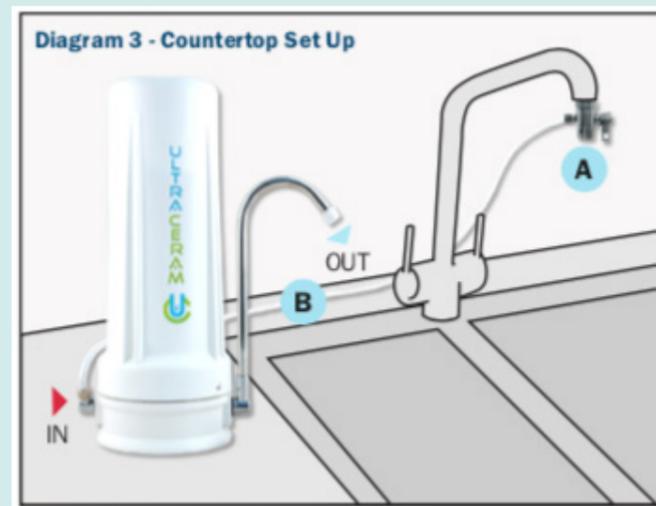
Mob 0432 536 281

## WHAT DOES PARTICIPATING INVOLVE?

### ➤ Using a water filter

If you choose to participate, your baby will be enrolled in this study at 6 months until your baby turns 18-months. Once enrolled you will receive a benchtop water filter fitted to the kitchen tap, which contains a carbon block that removes chlorine, heavy metals and pesticides for your tap water (pictured here). It doesn't remove fluoride which is important for dental health. It fits neatly to the kitchen tap and is easily removed.

We request that families use the water filter to prepare any drinks for their infants wherever possible, for a total duration of 12-months.



As this is a medical trial, your baby will be randomly assigned (like flipping a coin) to one of two groups. Neither you nor the investigators will be able to choose which group you will be in:

Group 1 – Filtered water group

Group 2 – Control group

The control group will receive sham filters that do not remove anything from the tap water.

At the end of the study you get to keep the water filters and we will replace any sham filters.

### ➤ Providing a stool sample

You will be mailed a swab kit to take a small sample of poo from babies' nappy, and an envelope to mail this to the laboratory to measure the gut bacteria. Families will be asked to do this on 3 occasions – at 6 months of age, 12 months of age, and again at 18 months of age, (pictured below).

The laboratory doing measuring the gut bacteria is a commercial company called MICROBA. At the end of the study, MICROBA will provide you with a personalised report on the unique composition of your child's gut bacteria, and tips to achieve a better balance between desirable and less desirable bacteria in the gut. You can share your reports with your health practitioner and learn some of the latest science.



To activate your kit you need to use MICROBA's website. You can consent to sharing your child's microbiome data with MICROBA for their own research into gut bacteria and health. You are free to decide whether to do this and it will not interfere with TUMS in any way.

### ➤ Complete our questionnaire

We will text you a link to a short questionnaire (5 minutes to complete) which you can complete on your smart phone. Data we collect will be stored securely in the ORIGINS databank.

### ➤ Have your water tested

An investigator from our team will visit you at your home on one occasion to take a sample of your tap water (about 1 cup of water). This will be taken to a lab for chemical analysis.

### ➤ DNA test

Some mothers have a mutation in a gene called FUT2, known as 'secretors' which is common in many populations. This mutation alters the composition of certain sugars in breastmilk and is known to influence babies gut bacteria. We will measure the FUT2 gene sequence in mothers enrolled in the study from the samples you provided to ORIGINS to determine which children had secretor mothers. This will help us ensure our study is not biased.

### ➤ Other information we collect about you

We will request information about home environment, family structure, diet, breastfeeding, medication use, formula use, illnesses and clinical assessments through surveys already administered by the ORIGINS Project. We will request access to these data to help identify links between lifestyles and the friendly gut bacteria. We may also seek approval to access biological samples that have been previously provided to ORIGINS, including but not limited to blood, serum, swabs, stool for the purpose of exploring links between the gut bacteria and markers in these tissues.