

# PARTICIPANT INFORMATION SHEET - PARENT OR LEGAL GUARDIAN

Centre for Microbiome Research  
Queensland University of Technology  
Faculty of Health  
School of Biomedical Sciences

QUT Ethics Approval Number 7414

## Research Team

|                      |                        |                       |                        |
|----------------------|------------------------|-----------------------|------------------------|
| Prof Gene Tyson      | Principal Investigator | Dr Asha Bowen         | Associate Investigator |
| Dr Simon McLroy      | Associate Investigator | Prof Benjamin Howden  | Associate Investigator |
| Dr Ben Woodcroft     | Associate Investigator | Dr Elise Pelzer       | Associate Investigator |
| Dr Allison McInnes   | Associate Investigator | Dr Emily Hoedt        | Associate Investigator |
| Ms Charlotte Vivian  | Biobank Manager        | Dr Alexei Chklovski   | Associate Investigator |
| Dr Peter Sternes     | Associate Investigator | Ms Melody Dobrinin    | PhD Student            |
| Dr James Volmer      | Associate Investigator | Ms Camila Pintos      | PhD Student            |
| Dr Kaylyn Tousignant | Associate Investigator | Ms Annie Xu           | PhD Student            |
| Dr Suzanne McCusker  | Associate Investigator | Ms Katherine Barlow   | PhD Student            |
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| Prof Gerald Holtmann | Associate Investigator | Ms Madeleine Yule     | Research Assistant     |
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| Dr Nicola Angel      | Associate Investigator | Dr Pam Engelberts     | Postdoctoral Fellow    |

## Introduction

This is an invitation for your child or dependent to take part in the Australian Human Microbiome Biobank research study.

Each of us is home to trillions of microorganisms that play an important role in our health and wellbeing, but our understanding of how they do this remains limited. This research project aims to collect a range of microorganisms that live in and on the human body and grow them in the laboratory so that we can study the ways they influence our health and how they can be used to treat disease.

This Participant Information Sheet and Consent Form tells you about the research project. It explains the tests and research involved. Knowing what is involved will help you decide if you want your child or dependent to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not your child or dependent can take part, you might want to talk about it with a relative, friend or local doctor.

Participation in this research is voluntary. If you don't wish for the child or dependent take part, they do not have to. They will receive the best possible care whether or not they take part.

If you decide you want your child or dependent to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to the child or dependent take part in the research project
- Consent to the child or dependent having the tests and research that are described
- Consent to the use of your child or dependent's personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

### What is the purpose of this research

The community of microorganisms living in and on the human body – known as the human microbiome – plays an important role in our health and wellbeing. These microorganisms make compounds that can influence your metabolism, immune system and even mental health, among other functions. However, we are unable to grow most of these microorganisms in the laboratory, making it difficult to study the diverse ways they affect human health. The purpose of this study is to create a collection of microorganisms from the human body, called the Australian Human Microbiome Biobank, so that researchers can study them in the laboratory to get a better understanding of how they influence health and disease. This knowledge may help researchers develop new ways to improve our health and wellbeing or to diagnose and treat a range of human diseases.

### What is a biobank?

A biobank is a collection of samples and health information donated by participants for the purpose of research. Researchers can then use these samples to generate and test new hypotheses in the laboratory. In this project, only the microorganisms found in your child or dependent's samples will be added to the Australian Human Microbiome Biobank; none of their human cells will be kept for future studies. The Biobank will be housed at Queensland University of Technology's (QUT) Centre for Microbiome Research (CMR), which is located at the Translational Research Institute (TRI) in Brisbane, Queensland.

### What does participation in this research involve?

If you choose for your child or dependent to take part in the Australian Human Microbiome Biobank, you will be required to sign a consent form on their behalf prior to any study assessments being performed. You will also be asked to get consent from your child or dependent if you judge them to be of sufficient maturity. Your child or dependent will then be asked to provide a stool sample and/or skin and mouth swab sample using the collection kit and instructions provided to them, either at home or at the Translational Research Institute (TRI). Female adolescents who have an established menstrual cycle will also be given the option to donate a vaginal microbiome swab sample, with parental or guardian consent. In these cases, you and your child or dependent can let our team know if you would prefer a female member of our research team to discuss the research with and to hand samples to.

Sample donation can be done at you and your child or dependent's own convenience, and samples can be dropped off at the CMR laboratory, which is located on Level 3 of TRI. Our team will organise a parking spot for your visit to TRI. If you and your child and dependent are unable to travel to TRI or would prefer to post their sample, we will provide them with a pre-paid envelope addressed to our laboratory along with their collection containers.

Your child or dependent will also be asked to complete a questionnaire that asks about their age, gender and general health; it is up to your discretion if they complete this alone or under your supervision. It is estimated that it will take up to two hours of you and your child or dependent's time to discuss the project with the research team, collect and donate their sample and fill out the questionnaires, plus any time it takes to travel to TRI. There are no costs associated with participating in this research project, nor will your child or dependent be paid. While we are unable to reimburse you or your child or dependent for any travel costs associated with their participation in this study, we will organise free parking at TRI to use while they donate their sample.

You may be contacted in the future and asked if your child or dependent wishes to donate another sample, if you consent to this. Participants who are under 18 at the time of sampling will also be re-contacted when they turn 18 and provided with an adult Participant Information Sheet and Consent Form so that consent can be sought directly from them. Participation in any follow up activities is entirely voluntary and a decision regarding your child or dependent's involvement can be made at time of contact. You may be contacted using the email address or phone number provided, and a maximum of three attempts to contact you will be made. Non-participation in follow-up activities will not affect you or your child or dependent's relationship with Queensland University of Technology in any way.

### What does my child or dependant have to do?

**Australian Human Microbiome Biobank**  
Centre for Microbiome Research, QUT  
Level 3, Translational Research Institute,  
37 Kent Street, Woolloongabba, QLD, 4102

PH: (07) 3443 7344  
Email: [admin@ahmb.com.au](mailto:admin@ahmb.com.au)  
[www.ahmb.com.au](http://www.ahmb.com.au)

If you choose for your child or dependent to participate in this study, they will be asked to provide the samples as described above. Your child or dependent can choose which samples they are willing to contribute, and they are not required to donate more than one type of sample. There is nothing they are required to change in their daily activities, including but not limited to exercise or sport, dietary habits, or medications prescribed by their physician, in order to participate in this research.

### **Other relevant information about the research project**

Because this project aims to collect as many different microbial species as possible, there is no limit to the number of people that can take part in the study. There are no specific study groups, and we are accepting samples from anyone who would like to participate and from any location in Australia. Our team includes researchers and clinicians from across Australia, including at the Queensland University of Technology, University of Queensland, University of Newcastle, Telethon Kids Institute, University of Melbourne and Microba Life Sciences.

### **Does my child or dependant have to take part in this research?**

Participation in any research project is voluntary. If you do not wish for your child or dependent to take part, they do not have to. If you decide for your child or dependent to take part and later change your mind, they are free to withdraw from the project at any stage.

If you do decide for your child or dependent to take part, you will be given this Parental/Guardian Participant Information Sheet and Consent Form to sign and you will be given a copy to keep. Your decision whether to have your child or dependent take part or not to take part, or to take part and then withdraw, will not affect their routine treatment, their relationship with those treating them or their relationship with Queensland University of Technology or any of our collaborating institutions.

### **What are the possible benefits of taking part?**

This biobank is not anticipated to provide your child or dependent with any direct or immediate benefit. However, they will be able to feel like they have contributed to advancing our understanding of the way the microbiome influences human health. We are very grateful for you and your child or dependent's time and interest in participating and would be happy to share future research that may come out of this project with you and your child or dependent. Please let us know if you would like to find out more about the research that is being undertaken.

### **What are the possible risks and disadvantages of taking part?**

Microbiome sampling is minimally invasive and low risk, although some participants may experience a level of discomfort associated with sample collection. We do acknowledge the time required for you and your child or dependent's involvement may be a burden. As mentioned above, we are happy to offer an at-home donation option to reduce the amount of time that is required. We do not anticipate any data collected from the study to be able to diagnose previously unknown conditions.

### **What will happen to your child or dependant's sample?**

Your child or dependent's sample will be processed to separate human and microbial cells, and only microorganisms collected from their sample will be included in the biobank. Their cells (including their DNA) will not be analysed or included in the biobank. Their sample will also be deidentified, and access to any identifiable or potentially identifiable data will be limited specifically to investigators of the project (namely Prof. Gene Tyson, Ms Charlotte Vivian, Dr Kaylyn Tousignant and Dr Suzanne McCusker) to ensure their information remains confidential.

Various laboratory techniques may be used to study the microorganisms present in your child or dependent's sample(s); however, we are unable to specify exactly which techniques will be used in advance. By consenting to this research, you are consenting to the use of your child or dependent's sample for a range of unspecified techniques to investigate which microorganisms are present in their sample, what functions they perform, and to grow these microorganisms in the laboratory. Following the initial processing and analysis of their sample,

microorganisms from their sample and associated questionnaire data will be stored indefinitely in a biobank and databank managed by CMR at QUT. Any unused sample (e.g. stool) will be frozen and stored at CMR; these samples will only be used by CMR researchers who may wish to re-isolate species that weren't captured during the initial processing.

Researchers and commercial entities who wish to use microbial isolates from the biobank in future studies may apply to the Australian Human Microbiome Biobank Executive Committee; this Committee will make decisions about how these microorganisms and linked data will be used (custodianship). Your child or dependent's identity will not be available to third parties who wish to access microorganisms from the biobank. If you do not wish for your child or dependent's sample to be kept and used for future studies, please notify the team when your child or dependent donates their sample and it will be destroyed in line with human tissue disposal regulations following the initial analysis.

### **Are there financial implications for my child or dependent?**

The Australian Human Microbiome Biobank will be a resource for external researchers and commercial entities who wish to purchase microbial isolates from the biobank to study in their own laboratories. There is the possibility that microorganisms from your child or dependent's sample may be used for the development of commercially viable products or medical treatments. This means that in the future, companies may benefit financially from this research project if, for example, the project assists the company to develop new health products or therapies. However, you and your child or dependent will not be able to claim financial benefit from any discoveries arising from the use of their samples.

By consenting for your child or dependent to take part in this research project, you agree that microorganisms collected from their sample(s) (or data generated from analysis of these microorganisms) may be provided to companies in the future.

### **Banking of health information**

The health information we will collect and store in a bank for research includes basic information, such as age and general health information that you (and/or your child or dependent) have provided in the health questionnaire. Once all personal identification is removed, the information might be used or released for other purposes without asking you but will be completely non-identifiable (anonymous). Results of the research project may be presented in public talks or written publications, but information will not be presented that identifies the participant.

### **What if I withdraw my child or dependent from this research project?**

If you decide to withdraw your consent for your child or dependent from this research project, please notify a member of the research team. You can withdraw from the research project at any time without penalty and any unused samples will be destroyed. However, you should be aware that microorganisms collected from your child or dependent's sample(s) and associated data up to the time you withdraw will form part of the biobank. If you do not want them to do this, you must tell the research team before your child or dependent joins the research project.

### **What happens when the research project ends?**

Currently there is funding to establish the Australian Human Microbiome Biobank over the next three years. However, given the nature of the biobank, there is no project end date, and the biobank will continue to be operational indefinitely.

### **What will happen to information about my child or dependent?**

By signing the consent form, you consent to the relevant research staff collecting and using personal information about your child or dependent for the research project. Any information obtained in connection with this research project that can identify your child or dependent will remain confidential, and their sample will be linked to a deidentified participant ID. Researchers who access isolates from the biobank will not have access to your child or dependent's identity, which is kept in a secure location and only accessible by the study investigators listed above (Prof. Gene Tyson, Ms Charlotte Vivian, Dr Kaylyn Tousignant and Dr Suzanne McCusker). Your child or dependent's

information will only be used for the purposes outlined in this project and it will only be disclosed with your permission, if it is to protect your child/dependent or others from harm, or if a regulatory or monitoring body such as the ethics committee requests it.

Microorganisms collected from your child or dependent's sample will be stored indefinitely in a biobank that will be made available to external researchers, along with a databank that includes information about the microorganism and details on what body site it was collected from (e.g., gut or skin). Each microorganism will include details on the age, gender and disease status of the donor, but all data will be deidentified so that researchers will not know who the isolate came from. Additional health information associated with their sample will be supplied as needed, but personal identification will not. Any data collected as part of this research project will be stored securely at QUT for a minimum of 15 years in accordance with QUT's Management of Research Data. We have assembled a Biobank Executive Committee who will monitor the research and ensure your child or dependent's information is protected in alignment with the National Statement on Ethical Conduct in Human Research from the NHMRC.

It is anticipated that the results of this research project will be published in peer-reviewed journals and/or presented in a variety of forums, such as at medical conferences. In any publication and/or presentation, only group results may be shared, and information will be provided in such a way that your child or dependent cannot be identified.

#### **Will I find out the results of the research project?**

Due to the long-term nature of the research, you and your child or dependent will not be notified of the future research done using microorganisms collected from their samples. This is because the results of this study are not likely to be of immediate relevance to your child or dependent. It will, however, generate a valuable resource that could ultimately be used to improve human health. When results are published in peer-reviewed journals or at conferences, it will be available to all participants via the Biobank website. Please let the research staff know if you are interested in learning more about the study results and we will be happy to provide information for the website.

#### **What if I have a concern or complaint regarding the conduct of the research?**

QUT is committed to research integrity and the ethical conduct of research projects. If you wish to discuss the study with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the QUT Research Ethics Advisory Team on +61 7 3138 5123 or email [humanethics@qut.edu.au](mailto:humanethics@qut.edu.au).

#### **Who is organising and funding the research?**

This research project is being conducted by the Centre for Microbiome Research at QUT. The work has been funded by a grant from the Australian Government Medical Research Future Fund, with additional contributions made by industry partners Microba Life Sciences, Cytek Biosciences and Illumina.

#### **Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Queensland University of Technology. This project will be carried out according to the National Statement on Ethical Conduct in Human Research 2023 from the National Health and Medical Research Council. This statement has been developed to protect the interests of people who agree to participate in human research studies.

#### **Further information and who to contact**

If you have any questions or require further information, please contact Charlotte Vivian, Biobank Manager, at [charlotte.vivian@qut.edu.au](mailto:charlotte.vivian@qut.edu.au) or by phone at 3443 7612.

**Thank you for helping with this research project. Please keep this sheet for your information.**