

# PARTICIPANT INFORMATION SHEET

QUT Ethics Approval Number 7414

Principal Investigator: Prof. Gene Tyson

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

## Research Team

Prof Gene Tyson	Principal Investigator	Dr Asha Bowen	Associate Investigator
Dr Simon McIlroy	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
Prof Trent Munro	Associate Investigator	Ms Siobhan Ingram	Research Assistant
Prof Fiona Wood	Associate Investigator	Ms Ana Astorga Alsina	Research Assistant
Prof Gerald Holtmann	Associate Investigator	Ms Madeleine Yule	Research Assistant
Dr Páraic Ó Cuív	Associate Investigator	Ms Vidya Gummagatta	Research Assistant
Dr Nicola Angel	Associate Investigator	Dr Pam Engelberts	Postdoctoral Fellow

## Introduction

You have been invited 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 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 to 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 to take part, you don't have to. You will receive the best possible care whether or not you take part.

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

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

You will be given a copy of this Participant Information Sheet 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 produce 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 samples will be added to the Australian Human Microbiome Biobank; none of your 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, Australia.

### What does participation in this research involve?

If you choose to take part in the Australian Human Microbiome Biobank study, you will be required to sign a consent form prior to any study assessments being performed. You will then be asked to provide a stool sample and/or skin, mouth or vaginal swab sample using the collection kit and instructions provided to you, either at home or at TRI. Please let us know if you would like to discuss the sample donation procedure with a male or female member of our research team and we are happy to accommodate.

Sample donation can be done at your 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 are unable to travel to TRI or would prefer to post your sample, we will provide you with a pre-paid envelope addressed to our laboratory along with your collection containers. You will also be asked to complete a questionnaire that asks about your age, gender and general health. It is estimated that it will take up to two hours of your time to discuss the project with the research team, collect and donate your 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 you be paid. While we are unable to reimburse you for any travel costs associated with your participation in this study, we will organise free parking at TRI for you to use while donating your sample.

You may also be contacted in the future and asked to donate another sample, if you consent to this. Participation in any follow up activities is entirely voluntary and a decision regarding your 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 your relationship with Queensland University of Technology in any way.

### What do I have to do?

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

### **Do I have to take part in this research?**

Participation in any research project 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 the project at any stage.

If you do decide to take part, you will be given this Participant Information Sheet and a Consent Form to sign and you will be given a copy to keep. 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 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 you with any direct or immediate benefit. However, you will be able to feel like you have contributed to advancing our understanding of the way the microbiome influences human health. We are very grateful for your time and interest in participating and would be happy to share future research that may come out of this project with you. 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 your involvement may be a burden. As mentioned above, we are happy to offer an at-home donation option to reduce the amount of your 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 my sample?**

Your sample will be processed to separate human and microbial cells, and only microorganisms collected from your sample will be included in the biobank. Your cells (including your DNA) will not be analysed or included in the biobank. Your 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 your information remains confidential.

Various laboratory techniques may be used to study the microorganisms present in your 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 sample for a range of unspecified techniques to investigate which microorganisms are present in your sample, what functions they perform, and to grow these microorganisms in the laboratory. Following the initial processing and analysis of your sample, microorganisms from your 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 Executive Committee will make decisions about how these microorganisms and linked data will be used (custodianship). Your identity

will not be available to third parties who wish to access microorganisms from the biobank. If you do not wish for your sample to be kept and used for future studies, please notify the team when you donate your sample and it will be destroyed in line with human tissue disposal regulations following the initial analysis.

### **Are there financial implications for me?**

The Australian Human Microbiome Biobank will be a resource for 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 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 will not be able to claim financial benefit from any discoveries arising from the use of your samples.

By taking part in this research project, you agree that microorganisms collected from your 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 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 from this research project?**

If you decide to withdraw your consent 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 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 you join 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 me?**

By signing the consent form, you consent to the relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential, and your sample will be linked to a deidentified participant ID. Researchers who access isolates from the biobank will not have access to your 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 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 you or others from harm, or if a regulatory or monitoring body such as the ethics committee requests it.

Microorganisms collected from your 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 your 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 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 you cannot be identified.

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

Due to the long-term nature of the research, you will not be notified of the future research done using microorganisms collected from your samples. This is because the results of this study are not likely to be of immediate relevance to you. 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.**