

**Melbourne School of Psychological Sciences
Plain Language Statement**

**PROJECT TITLE: Mapping the State of Our Microbes:
The Victorian Oral Microbiome and Lifestyle Study.**

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You are invited to participate in a University of Melbourne research project that aims to better understand how the bacteria that live in our mouths (collected from saliva) vary with different lifestyles, diets, and backgrounds. The saliva collected acts as a snapshot of your microbes at the time of sampling.

The data collected will be used to contribute to academic research at the University of Melbourne. It will also be added to a dynamic visual installation in Melbourne Museum's *Gut Feelings* exhibition.

The project is interested in learning about how these bacteria vary depending on where we live (looking at different neighbourhoods, whether we live near parks or farms), and health behaviours (such as dental care and antibiotic use).

You have been invited to participate because you have expressed interest, and can visit the museum. Participation is open to all visitors; however, a good understanding of written and spoken English is needed to provide informed consent (as explained below) and to answer the questions. People under 18 years of age require a parent or legal guardian to provide written consent for them at the museum. Those under 12 years of age will need a parent or legal guardian with them to take part.

What will I be asked to do?

This project takes about 25 minutes to complete while you are at the museum. It involves a questionnaire, height and weight measurement, and dribbling saliva into a plastic tube. If you are interested, you can also choose to complete a longer (at home) questionnaire later, in your own time.

There are two parts to the process. These are described below.

Part 1: At the Museum

Step 1. Research staff will talk to you about all the steps involved.

They will also ask you some questions, for example, have you had anything to eat, drink, smoke, exercised heavily or brushed your teeth in the 20-30 minutes prior? If so, you will be asked to wait or come back in 20 minutes.

Step 2. Research staff will ask you to read the rest of this document.

Step 3. Research staff will discuss this document with you to make sure you understand what is involved so you can decide whether or not you would like to take part.

Step 4. Research staff will then ask you to sign the Consent Form (required).

Step 5. Research staff will ask you to provide your contact details, and you will also be asked if you consent to being contacted in the future (optional).

Step 6. You will be asked to indicate if you consent to three optional points (described below).

Optional points on Consent Form. Do you consent to:

A. *your child(ren) taking part?*

If you do, and your child(ren) agree, they can also take part. You will need to participate with them and supervise children under 12 years. Children will be invited to complete the saliva collection, and height and weight measurements. You will be invited to complete a brief questionnaire for each child, via an email link sent to you after your visit. You will have two weeks to complete it.

If your child(ren) are 12 to 17 years of age, you may consent to them participating without you, and completing their own questionnaire, saliva, and height and weight measurements; however, you will need to be present to provide consent and supervision at the museum.

B. *having your home address matched to neighbourhood information?*

This includes Australian census data for neighbourhoods (not individual homes) as well as local government data, to explore relationships with how different environments influence what bacteria are present in people's mouths. *Please note that your address, and any other identifying information, will not be stored with your research data (i.e., saliva, questionnaire, height, and weight data).* Your identifying information will remain confidential. You may also choose to only have part of your address matched.

C. *the use of your research data (i.e., saliva, questionnaire, height, and weight data), with all identifying information removed, in future related research at the University of Melbourne?*

Related research will be restricted to the study of salivary microbes and their function, related to health, diet and lifestyle. All such future research would need to be approved by the University of Melbourne Human Research Ethics Committee prior to proceeding.

Step 7. You will be given a saliva collection tube with a barcode on it. This barcode will match the information you provide while keeping your name and other identifying information confidential.

Step 8. Height and weight measurement. Research staff will guide you through this. You have the option of removing your shoes before stepping on the scales. Measurement is done automatically by the device. Your height will be measured by soundwaves, which you won't be able to hear. Your height and weight will not be displayed to others present.

Step 9. Questionnaire. Research staff will select your barcode number on an iPad screen before you begin the questionnaire. Questions will be asked via the iPad, and will ask about your background (e.g. where you and your parents were born), your lifestyle (e.g. family, pets, jobs), your diet, your health, and your health behaviours. The questionnaire takes about 10-15 minutes to complete. You can read over the questionnaire before you consent, if you prefer. You can skip any question by selecting, 'prefer not to say'. You can ask research staff for help at any time.

Step 10. Saliva sample. At the end of the questionnaire, the iPad will display instructions on how to provide your saliva sample. Instructions are also provided on the last page of this document. You will dribble saliva into your collection tube for two minutes. Materials will be provided to make this clean and safe.

Please note that some physical conditions and medications may make it more difficult to produce saliva, and you may wish to consider this before choosing to take part. Conditions can include

dehydration, diabetes, low blood pressure, sinusitis, and hormonal imbalances. Medications can include anti-depressants, antihistamines, decongestants, and high blood pressure medication. Talk to research staff if you'd like additional time for any reason.

This completes all of the tasks at the museum.

Part 2. At home questionnaire (optional)

If you are 18 years of age or older and express interest in completing the longer follow up questionnaire, you will be emailed a web link in the days following your visit to the museum. You can complete this questionnaire online at a location of your choosing, either on a computer or mobile device. The at home questionnaire needs to be completed within two weeks of your visit to the museum so that it is relevant to the other information you provide.

This optional questionnaire will ask for more detailed information about your health, diet, functioning, mood and gut health. It will take approximately 90 minutes to complete, but can be done in several sittings.

What are the risks?

There are a few risks in participating in this study that you should be aware of. The collection of saliva samples and the measurement of height and weight may be uncomfortable or embarrassing for some people. Saliva collection will be in a public space, but you can choose to turn away from others. Detailed instructions to help make the process quick and clean are provided (see last page of this document). Gloves are provided, and hand sanitiser will be available. Your height and weight will be measured discretely.

Another potential risk involved in participating in this study is the inconvenience and burden involved in completing the questionnaires and saliva sample. It will take about 25 minutes for most people. The optional at home questions take longer, about 90 minutes for most people. You can complete the at home questionnaire in multiple sittings, on your preferred internet accessible device.

Some questions address potentially sensitive topics, and the at home questionnaire addresses potentially distressing topics relating to your mental health. The questions asked are commonly used in research by the University of Melbourne, and experiencing distress is rare. You do not have to answer any questions that you do not feel comfortable with, and all questions have a 'Prefer not to say' option. At home questionnaire participants will receive information with contact details for health and mental health services and further information. We will also provide this information to anyone who requests it.

Please note that you will be contacted by research staff from the University of Melbourne if you provide information that indicates that your life, or someone else's life, is at risk; however, for the at home questionnaire it may be up to one week for your responses to be processed. **If you are experiencing emotional or mental health difficulties, please contact LifeLine (13 11 14) or make an appointment with your general medical practitioner (i.e. your GP). You can also contact the research team (Dr Julian Simmons [03] 9035 8318; jgs@unimelb.edu.au or Ms Djamila Eliby, [03] 9035 4142; vic-spit@unimelb.edu.au) if you wish to discuss any concerns, regardless of whether you participate in all or some aspects of the project.

Please note that you do not need to complete any aspect of the project you do not wish to, and are free to change your mind and withdraw at any time. You are also free to stop at any time. Please let us know if you need to take a break.

As is noted for all research projects, there may be unforeseen or unknown risks. In the very unlikely event that you suffer an injury because of participating in this project, the public health service will provide hospital care and treatment at no cost to you. Please note that this may not

apply if you do not have an Australian Medicare card, such as if you are visiting Australia. Please discuss this with research staff if this applies to you, or you are unsure.

Are there any risks with the saliva samples?

There is a small risk of exposure to other participants' saliva, which carries a risk of infection. All participants will be provided with instructions on safe collection techniques, and provided with gloves, and hand sanitiser if requested. You will not need to touch anything after providing your saliva sample, and can drop it into a collection facility touch free. Saliva sampling is the last step participants complete at the museum. All equipment will be cleaned with ethanol wipes after each participant.

What happens if something unusual is found in my saliva?

There is a small chance that the saliva sample may reveal the presence of health concerns, such as bacterial infection. In these circumstances, results will be reviewed and, where required, you will be contacted and advised to seek medical follow up with your GP. Please note that these results may not become available until some months after you provide your sample. Speak with your GP if you have any health concerns.

What are the benefits?

No direct benefits to you are expected, however there are some indirect benefits. The University of Melbourne researchers conducting this project hope to increase their understanding of the relationships between the bacteria of the mouth with diet, health, lifestyle, and neighbourhoods across Victoria. The project will also look at antibiotic use and relationships with salivary bacteria. The University of Melbourne hope to apply the findings of this study to the design of future research studies exploring the relationships found, and what can be done to improve people's health.

For those participants who complete the longer at home questionnaire, you can choose to receive a free dietary analysis based on the dietary questionnaire that you complete, and information about the microbial profile of your saliva from the University of Melbourne. The analysis of the diet questionnaire provides information about your food intake over the past month, including things such as vegetables, sugar, fibre, protein, and fats, and how your daily intake compares to Australian nutritional guidelines. The microbial profile will provide information on the broad types of bacteria, and their relative abundances, found in your saliva.

You will not be financially reimbursed for your time, but we do hope you will enjoy taking part.

You can choose to be informed of the study results, via regular study newsletters from the University of Melbourne, on the Contact Details form. These newsletters will update you on study progress and key findings, including links to study publications (e.g. peer-reviewed journal articles, media coverage). The summary findings reported will show all participants, not your individual results.

This study is funded by the University of Melbourne, and specifically the Melbourne School of Psychological Sciences, the Melbourne Dental School, and Chancellery (Research and Enterprise), and supported by Museums Victoria, the Peter Doherty Institute for Infection and Immunity (the University of Melbourne) and Callpoint Spatial Pty Ltd.

How will my confidentiality be protected?

Any information collected for this research project will be treated as confidential. Information can only be disclosed with your permission, except as required by law. Confidentiality may be broken if you share information indicating possible harm to yourself or others, or where mandated by law.

All information will be stored securely in locked cabinets or electronically in password-protected databases that are located on servers behind firewalls. Data will initially be stored at the Melbourne Museum, and then transferred (within one week) to the Melbourne School of Psychological Sciences at the University of Melbourne. Access to computer files will be available by password only, and only named researchers will have access to these files. All saliva samples will be transported to Psychological Sciences for storage at the end of each collection day. Samples will then have the different types of bacteria identified and numbers estimated at the Doherty Institute.

All information you provide will be de-identified, but can be re-identifiable. This means that we will remove your name and other identifying details and link it to the barcode. Only the research team can match your details to the barcode, and only if it is necessary to do so. In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access and correct the information we collect and store about you. Please contact project staff at the University of Melbourne (vic-spit@unimelb.edu.au) if you would like to access this information.

The University of Melbourne will keep all information until 15 years after the last publication based on the data. After this time, it will be destroyed. The information you provide will not be used again for future research, unless you provide the optional consent for its use in future related research on the Consent Form.

Please note that when the results of this project are written or talked about, information will be communicated in such a way that you cannot be identified.

What if I want to withdraw from the Research?

Participation in this research is completely voluntary. You are free to withdraw at any time and to have your questionnaire and height/weight data, and your saliva sample deleted or disposed of. This would have no effect on your relationship with any member of the University of Melbourne or Museums Victoria. It would not affect any treatment that you would otherwise be eligible for.

Where can I get further information?

If you have not understood any of this information please speak to one of the research staff at the exhibit, or contact any of the researchers listed above. You can also visit the study website: <https://psychologicalsciences.unimelb.edu.au/research/vicspit/>

This research project has been approved by the Human Research Ethics Committee of the University of Melbourne. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Office for Research Ethics and Integrity, the University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or Fax: +61 3 9347 6739 or Email:

HumanEthicscomplaints@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence please provide the name of the research team, the study name or ethics ID number (HREC# 1853257) of the research project.

How do I agree to participate?

If you wish to participate, please let one of the research staff know, and they will assist you with the next steps. They are located next to the *Gut Feelings* exhibition. Please note that the research will only be conducted on specific dates. See the study website for details.

<https://psychologicalsciences.unimelb.edu.au/research/vicspit/>

Saliva Collection Instructions

Please read all of these instructions before you start. Let us know if you have any questions or if any of the information is unclear.

1. Open the zip lock bag and remove the gloves. (Gloves are made from nitrile)
2. Put on the gloves.
3. Remove the collection tube from the bag. Do not put down on the bench.
4. Unscrew the collection tube cap and place it on the bench with the top of the cap sitting on the bench.
5. Remove the straw from the bag and place one end of the straw in collection tube.
6. Place your lips over the other end of the straw – Do not start drooling just yet!
7. When you are ready, start the timer on the iPad with your free hand.
8. Once the timer has started, allow saliva to gather in your mouth. Do not swallow. Once you feel the saliva build up in your mouth, tilt your head forward, and allow the saliva to flow down the straw and into the tube.
9. Gently dribble saliva down the straw and into the tube for two (2) minutes.
Some tips:
 - a. Do not spit or blow, as this fills the tube with bubbles.
 - b. Relax your jaw by letting your teeth separate and jaw drop.
 - c. Chew or move your tongue around gently until you feel saliva building up in your mouth. Keep chewing and don't swallow.
 - d. It can help to think of your favourite food, or lemons.
10. Keep drooling until the timer is done (two minutes).
11. When the timer ends, push the straw into the tube.
12. Taking care not to spill your sample, pick up the cap and screw it onto the sampling tube. Make sure it is secure and tight. **Please don't put your collection tube onto the bench.**
13. Deposit your collection tube into the drop point.
14. Remove your gloves.
15. Give your gloves and bag to research staff. Please keep them separate, as it helps us with recycling them.

Please let staff know if you have any questions.

Also, please let us know if you haven't been able to provide a saliva sample (or it's very small) and you're happy to provide more saliva. We can give you more time. You are not required to provide more, so it is only if you choose to do so.