

Informed consent form

Please read through the entire form. If you agree and provide consent to be a part of the study, please provide your name, signature, date and time.

Thank you!

STUDY INFORMATION AND INFORMED CONSENT SHEET

CSIR Microbiome Mapping Initiative (CMMI)

Study title: Snapshot of the gut microbial diversity of an urban South African population: Impact of diet, lifestyle and socioeconomic status

Greetings,

You are being asked to participate in a research study conducted by Claudine Nkera-Gutabara (PhD candidate) and supervisors Prof Scott Hazelhurst and Dr Robyn Kerr from the University of the Witwatersrand, in collaboration with Dr Jerolen Naidoo from the Bioengineering & Integrative Genomics Group (Next Generation Health Cluster) at the CSIR. We are conducting a research study to find out more about the trillions of bacteria and other organisms (called your microbiome) that live in your gut. You have been asked to participate in this study because your microbiome is unique - not the same as anyone else on earth. There will be approximately 400 participants in this pilot study at the CSIR campus and 1000s more from similar studies that are underway or have been completed in other countries around the world including the UK and USA.

The gut microbiome:

The human microbiome refers to the collection of microorganisms (bacteria, fungi, viruses etc.) that have evolved with humans to co-inhabit numerous sites within the human body like your gut, mouth, skin, lungs etc. In fact, the number of bacterial cells in the average human body outnumber human ones, with the accompanying genetic diversity resulting in the human microbiome being referred to as the 'second genome'.

The bacteria of the human gastrointestinal tract (GIT, i.e. stomach and intestines) in particular accommodates a large, dynamic and complex population of bacteria. The colonization of the GIT by these bacteria in early life has been shown to be crucial to the development of the immune system and metabolic function, while in adult life, the gut microbiome has been linked to a number of health outcomes, with the disruption of "core" bacterial populations correlated to various diseases and symptoms, such as irritable bowel disease, food allergies like gluten intolerance, obesity, diabetes, asthma, cognitive disorders and cardiovascular disease to name a few.

Purpose of the study:

Characterization of the gut microbiome, through the collection of faecal samples and the genetic identification of bacterial species, can help researchers begin to understand the relationship between the composition of the microbiome and health and disease.

The purpose of this study is to more accurately assess the differences between the types of gut bacteria present in different people and whether these differences can be attributed to specific lifestyle, diet, health, age or environmental exposures (known as metadata). The results will be used to create a database of bacterial genetic data and metadata about the participant supplying the sample, which can be used by other researchers for comparison

when they are studying the same type of sample in other scientific studies e.g. certain diseases where gut abnormalities are common.

This study is an important stepping stone towards South Africans being able to understand the relationships between our gut bacteria, lifestyles and environment and you can be a part of this. Additionally, all participants will receive a feedback report comparing your gut profile to other participants, as well as participants from similar studies across the globe, including North America and Europe.

Study procedures:

If you would like to volunteer to participate in this study, we would ask you to do the following:

- 1. Fill in a basic online questionnaire regarding medical information, cultural practices, your environment and lifestyle. This survey should take ~35 minutes to complete and can be completed over multiple sessions. Your information will be anonymised and you will be given a unique barcode.**
- 2. Using this barcode, you can then come to our stand at Knowledge Commons to collect your allocated faecal sample collection kit with gloves, collection tube, toilet hammock, instruction leaflet and a link to online support.**
- 3. You can then watch the online sample collection tutorial (<https://www.youtube.com/watch?v=a9WXUZNyrgg>) and use the information leaflet to easily collect your single scoop of a faecal sample.**
- 4. You will then return the sample collection tube to our stand at Knowledge Commons and your sample will be stored at our CSIR laboratory.**
- 5. DNA will be extracted from the sample and amplified by PCR (polymerase chain reaction) and then sequenced to see what bacteria are present and in what proportion in your sample.**
- 6. The sequencing results are processed through our bioinformatics pipeline for bacterial species identification and quantification. This microbial profile will be linked to your questionnaire through the unique barcode we initially provided.**
- 7. The anonymised data will be stored in a secure database and will be analyzed to identify potential links between different variables and the microbiome of study participants.**
- 8. Once the study is completed, we will provide individual reports for all the participants. We**

estimate that it will take ~6 months for you to learn the results of the initial bacterial diversity estimation.

Risks of being involved in the study:

There are no risks of being involved in this study to participants. As with general use of toilet facilities, please ensure that you wash your hands properly after sample collection and that you dispose of the waste and kit contents as described in the leaflet and the media links on the leaflet. Please use the gloves and spatula provided with the kit during the collection process and do not handle fecal matter by hand and do not store the fecal sample in your fridge or freezer. The sampling techniques have been used for ~10 years with no reported side effects. We do not examine any human DNA that may be in the sample so personal information about your genome will not be obtained. All data deposited in our database will be filtered of known human sequence data before being deposited. The investigation personnel have taken precautions to ensure that there is minimal risk of loss of confidentiality.

Benefits of being in the study:

There is no direct benefit to you for participating in this study. We believe that there may be natural curiosity to know what microbes are in your sample and how this compares to other people of the same gender and age from SA and around the world. The investigators, however, will learn more about the human microbiome in health and disease and provide a valuable resource for other researchers in other studies. Additionally, the success of this pilot study may allow the researchers to establish a larger scale study across SA contributing to a South African microbiome project.

Payment for participation:

You will not be financially compensated in this study and there will be no costs to you for participating.

Confidentiality: Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of de-identifying participants using a unique barcoding scheme to link participant metadata to their sample. All data collected will be stored on secure local databases and only accessed by authorized researchers. Your name and your personal details will remain private at all times.

By signing the consent form you will be allowing us to sequence the nucleic acids (DNA/RNA) and metabolites extracted from your faecal sample to identify the bacteria types and the number of them present in your gut. You will not benefit from the results. Your samples are completely de-identified from the start of the process. The data from the questionnaire along with the data on the bacterial species are the only information accessible to researchers, not your personal information (name, contact info etc.) None of the researchers involved at any stage of the sample processing and sequencing steps will have access to your personal information or identity (only unique tube IDs). We have made every effort to ensure that you cannot be identified from the data you supply about yourself but retaining critical information like gender, age without compromising your personal information or the data integrity. The

database housing the website and your information will be housed within the access controlled CSIR campus, will be encrypted and backed up regularly. De-identified data (sequencing and questionnaire information but not name and contact information) will be provided to the data analytics team for analysis. Your sample may be stored at the CSIR BIG laboratory for up to two months before it is processed together with a batch of other samples. Any excess/remaining samples will be disposed of immediately following the DNA extraction step. Your sample will only be used for this study and under the terms of the consent provided within this document.

Please Note: The sequencing is not for diagnostic purposes and does not target human DNA.

Participation and withdrawal

Participation is voluntary and you can choose whether to be in this study or not. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. The investigators may withdraw your sample from this research if circumstances arise which warrant doing so. These include circumstances where the integrity of your sample has been compromised. If you decide that you no longer wish to continue in this study, you will be requested to contact the Researchers by email to inform us of your intent to withdraw.

Contact details of researcher/s:

Student researcher: Claudine Nkera-Gutabara
Email: claudinenkera@yahoo.com
scott.hazelhurst@wits.ac.za
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Supervisor: Prof Scott Hazelhurst
Email:
Tel: 0117176181
PI/Supervisor: Dr Jerolen Naidoo
Email: jnaidoo@csir.co.za
Tel: 0128414507

Rights of research subjects

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, contact Dr Sandile Ncanana, the CSIR REC Secretariat, [R&DEthics@csir.co.za/012 841 4060] at the Research and Development Office.

Contact details of HREC administrator and chair - for reporting of complaints / problems:
This study has been approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, Johannesburg ("Committee"). A principal function of this Committee is to safeguard the rights and dignity of all human subjects who agree to participate in a research project and the integrity of the research.

If you have any concern over the way the study is being conducted, please contact the Chairperson of this Committee who is Professor Clement Penny, who may be contacted on

telephone number 011 717 2301, or by e-mail on Clement.Penny@wits.ac.za. The telephone numbers for the Committee secretariat are 011 717 2700/1234 and the e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

THE INFORMATION ABOVE WAS DESCRIBED TO ME, THE PARTICIPANT IN A LANGUAGE I AM IN COMMAND OF.

I hereby consent voluntarily to participate in this study:

- Yes
 No

Please note: For the following questions regarding sample and DNA consent, we require consent ("yes") in order to continue to the survey. If your answer is "no", this means consent is not given and the window will close.

All questions are in line with the information and consent sheet and approved by the Wits Health Sciences Medical Research Ethics committee.

Thank you.

CSIR Microbiome Mapping Initiative Study - Sample Consent Sheet

I agree to be a participant in the study. I understand that the study will involve the collection of samples and that details and purposes of this study have been explained to me. I understand that I have the right to refuse to participate in the study. I acknowledge that all procedure/tests on the samples have been or will be approved by the Human Research Ethics Committee of the University of the Witwatersrand. I agree to give a faecal sample

- Yes
 No

CSIR Microbiome Mapping Initiative Study - DNA Consent Sheet

I agree to be a participant in the study. I acknowledge that all procedure/tests on the stored DNA samples have been or will be approved by the Human Research Ethics Committee of the University of the Witwatersrand.

- Yes
 No

I am in agreement that my DNA may be stored and used for the purposes described above.

- Yes
 No

I am in agreement that the data generated from my DNA may be made available in a public domain without any identifiers.

- Yes
 No

I understand that every time a new study is done on my DNA, permission will be obtained from the ethics committee for the study to make sure that it is used only for the purposes stated above.

- Yes
 No

I understand that I will not benefit directly from the research done on my DNA.

- Yes
 No

I understand that I may withdraw from the study at any time.

- Yes
- No

Please provide your name below (this information will only be available to the researcher and will be de-identified and kept anonymous in the study)

Signature

Date and time:
