 **Participant Information Sheet**

**Study title: EM³ study: Microbiota of New Zealand Homes**

**Locality: Wellington, Auckland, Christchurch, Tauranga**

**Ethics Committee Ref.:** **19/CEN/76**

**Lead investigator: Prof Julian Crane Contact phone number: 04 918 5258**

You are invited to take part in a study about the Microbiota of New Zealand Homes. This Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can withdraw from the study at any time.

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| **What is the purpose of this study?** |

This study will look for the first time at the communities of microbes (fungi and bacteria) that inhabit our homes. It is now possible to look at many microbes in house dust by measuring traces of the chemicals that they produce. We are also studying whether any of these microbes or the chemicals they produce may have an impact on our health, and in particular our lung health. The study has two aims:

1. We want to survey a number of New Zealand homes and look and compare the levels and types of bacteria and fungi (the microbiota) that are found in environmental samples taken from homes. We are looking to recruit 250 homes into this aim of the study.
2. We also want to conduct a health survey of the occupants of some of these homes and see if there are any links between health and the microbiota of the home. We are looking to recruit 200 homes into this aim of the study. The homes would be selected based on the results from some of our environmental samples.

This study has been funded by the Health Research Council of New Zealand and has received ethical approval from the Central Health and Disability Ethics Committee (Ref: 19/CEN/76).

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| **What will my family’s participation involve?** |

If you are interested in taking part in this study, we would like to ask you some questions over the phone to see if you are eligible. If you are and you decide to take part, there are a range of questionnaires we would like you to answer and a visit to your home. The visit to your home would take about 90 minutes and involve a questionnaire about your home, four floor dust samples, which involves vacuuming a square metre of flooring, and three air samples being taken from your home, two indoors and one outdoors. We would also like to install a temperature and humidity monitor (Hobo) for 2 weeks, and petri dishes (small circular plastic dishes) to collect airborne dust, which we will temporarily attach to a wall in your home and we will ask you to mail back to us in a provided courier envelope. We would also like to take a measure of some of the chemicals in the air, called volatile organic chemicals, which would involve placing a small tube (Radiello cartridges) with the other sensors for 2 weeks. These would also be mailed back to us in the same envelope. We would also record some of the building characteristics of the home, such as building materials, moisture, temperature and humidity conditions, and look at ventilation in your home by measuring the performance of your extractor fans and range hood, if you have them. The data would be used by the researchers to compare these things to the types of bacteria and fungi we find and to see if there are differences between houses. We also ask everyone who is home and over 9 years of age to complete a voluntary breathing test called a FeNO test, which is an easy and quick test to measure your lung function by measuring how much lung inflammation you have. A picture of the equipment you would need to blow into is included below:



Once some of the environmental samples are analysed we would let you know whether you had been selected to be in the second part of the study, which would involve your family answering some health questionnaires. If you are willing, we would also like access to your general practitioner records and for one member of your household to carry out a blood test to look at markers of inflammation, and have a nasal swab taken, to look at the types of bacteria and fungi found in the nose.

We would also like your permission to add our study data to the Statistics New Zealand Integrated Data Infrastructure (IDI). The IDI contains information collected by the government and other agencies about you and your household, and includes such things as census data, hospitalisations and prescription data. The data is de-identified so nobody’s name is used, and nobody’s individual data can be looked at. When researchers look at the study data this is done on everyone’s data at once. Once the study data is added it cannot be removed. However, the data is only used by Statistics New Zealand and trusted researchers to produce statistics and research to benefit New Zealand. This is an optional part of the study; you can take part in the rest of the study but opt not to take part in this.

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| **Frequently asked questions** |

**Where and when will I see the research team?** The research team would arrange to see you for the visit at your home at a time that was convenient to you, and a time when most of your family would be home to carry out the FeNO breathing test. We try to group the visits so that we are in your area of the country in certain weeks. If you are selected for the health study, the health surveys can be carried out online at any time that works for you and your family members, or if you prefer, we can ask you the questions over the phone. There is one health questionnaire for each family member. Children aged 14 years and over would be asked to fill in their own questionnaire. For children under 14 years old, a parent can fill in their questionnaire.

**Who are the research team?** This study is being conducted by researchers from the Department of Medicine at the University of Otago, Wellington, however we are also enlisting other experts to help us with some parts of the study. Researchers from Building Research Association of New Zealand (BRANZ) will take the environmental samples and carry out the breathing test. The health surveys would be carried out by health researchers from the University of Otago.

**Can I take part in some of the study but not all?** There are some things that we need everyone to do. We need everyone to have environmental dust and vacuum samples taken, have the temperature and humidity monitor, the air monitor for volatile organic chemicals, answer the housing questionnaire, have building characteristics recorded, and a health survey. However, if you do not want to carry out the breathing test, or allow us to have access to your GP records, or carry out a blood test, or have the data linked from the study in the IDI, then you do not have to. We will ask you to read and sign a consent form, where you will be able to choose which of the parts of the study you want to take part in.

**What if some people in the house want to take part but not others?** We would like as many people to take part per household as possible, however, as long as we are able to take the environmental samples, and at least one person answers the house questions and health questions, then if the other household members don’t want to take part then they don’t have to. For those household members who do want to take part, we ask each individual person who is willing to take part to sign a consent form. Children under 16 need a guardian to sign a consent form, but we do ask for their assent also if they are over 8 years of age.

**Who has access to my information?** Only the research team directly involved in this study will have access to your personal information, which includes all the results from your environmental sampling, temperature and humidity monitoring as well as your responses to the questionnaires. No information that can identify you, your family or your house would be used in any reports or publications.

**Why do you want access to GP records?** If you are selected to take part in the health survey, then we will be asking you a number of questions about your health. If you are willing, we would like to also check your GP records to get a more thorough medical history, which would include prescribed medications, number of visits to your GP and any specialist referrals. We will ask you these questions too, but sometimes it can be difficult to remember what each family member has had and when, which is why we also like to check the doctor’s records.

**Why do you want to link the study data to the Statistics New Zealand IDI data?** Adding the study data to the IDI dataset enriches our data set in two ways. Firstly, it allows us to add in further information, such as the census data, to help us further explore and understand the microbiota results from our study. Secondly, as the data remains linked, other researchers could apply to use the data set in future studies, with Statistics New Zealand’s permission, to check for other possible associations in the data. As the data is ‘de-identified’ and held by Statistics New Zealand, the data would remain completely anonymous, nobody would be able to look up anyone individually to gain access about that household.

**What will be gained from the study?** Your participation in the study will allow us to gain valuable knowledge on the microbiota of New Zealand. For those participating in the health survey it will also allow us to gain knowledge about whether the levels of fungi and bacteria in homes have an influence on health. A $50 gift card will be given to each household at the first visit and another $50 gift card will be given at the end of your participation in the study as a small gesture of our appreciation.

**Will I receive the results of the study?** We can provide you with your results from certain parts of the study as they become available, such as some of the environmental samples and breathing test. However, the main study results would not be available until everyone has completed the study, the data analysis has been carried out and a scientific paper prepared. Once this is complete, we will recontact everyone to let them know what we have found.

**Will researchers discuss the building characteristics findings with us?** As the building characteristics that we measure are mostly visual, there is limited information our research team will be able to give you regarding their findings.  Any obvious potential issues identified will be mentioned verbally but may need further investigation by your own builder or assessor.

**What if something goes wrong?** We do not foresee any risks or side effects to your or your family’s health by participating in this study.

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

**Who do I contact for more information or if I have concerns?** If you would like to discuss any part of the research or your participation in it, please email em3.study@otago.ac.nz or phone or text our research staff on 021 279 3311. If you have any concerns or complaints about this study, please email Professor Julian Crane (em3.study@otago.ac.nz), principal investigator, University of Otago, Wellington or call him on 04 918 5258.

If you have any concerns regarding your rights as a participant in this study and you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on: Phone: 0800 555 050, Fax: 0800 2 SUPPORT (0800 2787 7678), Email: advocacy@hdc.org.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS, Email: hdecs@moh.govt.nz

The study has received approval from the Ngai Tahu Research Consultation Committee. For any questions regarding Māori cultural aspects of the study, please contact Nick Waipara on (09) 925 7000 or text 021 279 3311.