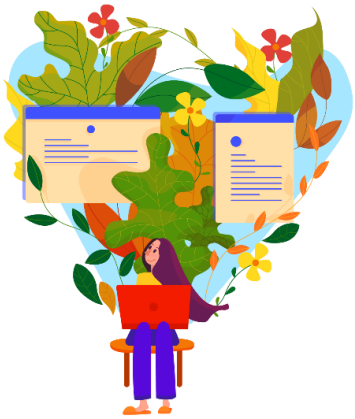
Biodiversity and Health Study: Information Sheet



Principal investigators:
Professor Jeroen Douwes – Research Centre for Hauora and Health, Massey University, Wellington
Professor Julian Crane – Wellington Asthma Research Group, University of Otago, Wellington
Dr Geoffrey Donovan – USDA Forestry Service, Portland, Oregon,USA
Dr Demetrios Gatziolis – USDA Forestry Service, Portland, Oregon, USA
Dr Thorsten Villiers Stanley – Department of Paediatrics and Child Health, University of Otago, Wellington
Dr Collin Brooks – Research Centre for Hauora and Health, Massey University, Wellington
Professor Geraint Rogers – South Australian Health and Medical Research Institute, Adelaide, Australia
Professor Bernhard Breier – School of Sport, Exercise and Nutrition, Massey University, Auckland
Professor John Potter – Research Centre for Hauora and Health, Massey University, Wellington
Dr Marine Corbin – Research Centre for Hauora and Health, Massey University, Wellington
Professor Chris Cunningham – Research Centre for Hauora and Health, Massey University (Māori cultural contact)

What is this study about?

We would like to invite you and your child to participate in a study that will assess how exposure to the natural environment affects childhood health. Previous studies suggest that exposure to a greater variety of plants, animals, and rural living may protect against several health conditions. We think this protective effect is because these environments have more microbial diversity. This study will investigate if environmental biodiversity is associated with differences in asthma and allergy prevalence, and also differences in environmental bacteria, gut and nasal bacteria, and specific immune responses in New Zealand children.

For this study to be successful, we need children with and without asthma and allergies to take part. If your child agrees to participate, they will be one of 900 children aged 6-11 years taking part. This study will help us find out more about how biodiversity may have health benefits, and may provide important new knowledge to help develop more effective strategies to prevent common health conditions such as asthma and allergies.

What will my participation involve?

Phase 1: All participants

Participation in this phase of the study consists of two steps:

Step 1 - Parents fill out the questionnaire. This survey may take 20-30 minutes to complete.

Step 2 - Child undergoes a non-invasive exhaled nitric oxide test (measure of airway inflammation) and skin prick test conducted by a trained research nurse (see next page). This may take 15-30 minutes to complete.

Please note that this study is entirely voluntary and your child can opt out of the study or taking part in any of the tests at any time.

Research Centre for Hauora and Health
Massey University – Wellington Campus

PO Box 756
Wellington, 6140
New Zealand

Administration
+64 (04) 979 3106
Direct Fax
+64 (04) 802 7120

Courier Address
Block 3, Level D
Entrance B, Wallace Street
Wellington, 6021
New Zealand

Internet
publichealth.massey.ac.nz

Study Coordinator Telephone
0508 ASTHMA (278 462)
asthma@massey.ac.nz

An exhaled NO (FeNO) test. This involves blowing into a specialised machine for several seconds, which allows us to assess airway inflammation. This procedure will take less than five minutes.

A skin prick allergy test. To do this, trained personnel apply small drops of liquid containing allergen on the skin of the forearm and then administer a small prick (this is almost painless, and just enough to break the skin) at each drop to see if there is an allergic reaction. This procedure will take less than 15 minutes. Some topical forearm itching and an insect bite-like reaction may occur with a positive test. Apart from an insect bite-like reaction (if the test is positive) adverse reactions to skin prick testing are extremely rare, and no serious allergic reactions have been reported despite extensive use in large groups of children.

Phase 2: 300 participants (selected from the initial 900 children)

From the initial 900 participants, 300 children who have lived in high, medium and low vegetation diverse areas from birth will be randomly selected and invited to take part in phase 2. Participation in this phase of the study consists of three steps (details below):

Step 1 - A blood sample, nasal swab and saliva swab will be collected by a trained research nurse. This can be done at Massey University (Wellington), a local pathology lab, school, or your home, and may take 5-10 minutes.

Step 2 - You and your child will be given a stool sample collection kit that can be used to collect a stool sample at home.

Step 3 - We will collect a sample of household and school dust, and in some cases, ask your child to wear an activity watch (Actigraph) to measure physical activity. We may also ask you to use a special doormat to collect dust and soil from your local environment.

A blood sample. This will be collected from your child's arm, and will be used to assess levels of proteins associated with allergy and inflammation. This procedure will take less than 5 minutes. Blood collection may be slightly uncomfortable, and may result in a temporary bruise.

A nasal and saliva swab. The nasal swab involves inserting a sterile nylon swab into your child's nostril, and gently rotating it. The saliva swab involves placing a sterile swab into your child's mouth, to collect an oral sample. These procedures will take less than five minutes, and the samples will be used to examine bacteria in the upper airways. Your child may feel a slight sense of discomfort, and stinging in their nose.

A stool sample. We will provide you/your child with a stool collection kit to collect a stool sample at home. This can be done at any convenient time, and then sent to us by post, or collected by our researchers. This sample will be used to examine bacteria in the gut.

Household and school dust samples. This will be carried out by trained field workers, and involves vacuuming areas of your house and child's school. We may also ask you to use a special doormat for a month in summer. These samples will provide information on the types of bacteria your child is exposed to.

Who pays for the study?

This study has been awarded funding from the Health Research Council and the Marsden Fund. Participation in our study will not incur any costs to your child. If participants complete clinical testing at our centre we will allow $20 per participant for each visit as a reimbursement for local travel costs. A koha (or gift) will be given to all participants as a token of appreciation for their participation.

What will happen with my information and my child's personal information?

All information collected during the study is confidential. Questionnaires will be seen by named researchers only. Both during the study and when the study is completed all questionnaires will be locked away in filing cabinets. In the case of unexpected or "abnormal" results, we would like your permission to send your child's results to their general practitioner (GP) as they may be useful for their future medical care. We would not send your child's GP any other results from the study. The results of the study will be published in scientific journals and a summary of the results will be provided to all study participants. **No individual information or names will be published**. *This project has been reviewed and approved by the Massey University Human Ethics Committee: Southern A, Application 19/76. If you have any concerns about the conduct of this research, please contact Dr Negar Partow, Chair, Massey University Human Ethics Committee: Southern A, telephone 04 801 5799 x 63363, email humanethicsoutha@massey.ac.nz.*

Disposal and storage of biological samples:

Your child's blood, nasal, and stool samples, and all environmental dust samples, will be stored for up to ten years and disposed of by the laboratory responsible for conducting specific analyses using established guidelines for discarding biological waste following completion of analysis. Nasal, stool, and enviromental samples may be sent overseas (UK or Australia) for bacterial analysis. We appreciate that you and your family may hold beliefs about a sacred and shared value for all or any tissue samples removed. The cultural issues associated with sending samples overseas for analysis and disposing and storing your child's samples will be discussed with your family/ whānau as appropriate. There is a range of views held by Māori around these issues; some iwi disagree with storage of samples citing whakapapa and advise their people to consult prior to participation in research where this occurs. However, it is acknowledged that individuals have the right to choose.

Future unspecified research:

As part of this study, you and your child have the option to agree for your child's remaining collected samples and data to be used by the current research team in New Zealand for future unspecified research. This may allow us to answer questions that may arise during the course of our study. Such research may include further immunological, inflammatory, genetic, and epigenetic analysis. If you agree to this, your child will not need to have any additional tests.

Your child's data and samples will be stored anonymously for up to 10 years and all future research will be subject to ethical review.

Consenting for future unspecified research is OPTIONAL and you and/or your child can withdraw consent at any time during or after the study. However, the research done on your child's remaining samples before you change your mind cannot be reversed. If you consent to your child's remaining samples being stored anonymously, you relinquish your right to withdraw consent in the future.

We will not contact you in the future regarding your child's stored biological samples. However, you can request information on the analysis of samples or future unspecified research at any time. Your decision regarding consent for use of your child's tissue samples for unspecified future research will in no way affect the quality of your child's current or future clinical care.

Your child's rights:

If you have any queries or concerns about your rights as a participant in this study you may wish to contact a Health and Disabilities Services advocate (telephone: 0800 37 77 66 or email: hdecs@moh.govt.nz). If there is a specific Māori issue or concern, please contact Professor Chris Cunningham (email: C.W.Cunningham@massey.ac.nz).

Your child has the right to:

- decline to participate
- decline to answer any of the questions
- stop the questionnaire/tests at any time
- withdraw from the study or parts of the study at any time either verbally or in writing
- be given access to a summary of the study findings when it is completed

Compensation

If physical injury results from your child's participation in this study, you should visit a treatment provider to make a claim to ACC as soon as possible. ACC cover and entitlements are not automatic and your claim will be assessed by ACC in accordance with the Injury Prevention, Rehabilitation and Compensation Act 2001. If your claim is not accepted you should immediately contact the researcher. The researcher will initiate processes to ensure your child receives compensation equivalent to that to which they would have been entitled had ACC accepted your claim.

Thank you very much for your time in considering this study.

We hope that with your help we can find more innovative and safe approaches to preventing and reducing allergies and asthma in New Zealand.

For further information or to discuss any queries that you may have about the study,

please contact the study coordinator on:

0508 ASTHMA

Email: asthma@massey.ac.nz

Research Centre for Hauora and Health
Massey University- Wellington Campus
PO Box 756
Wellington 6014
Fax: (04) 802-7120
http://publichealth.massey.ac.nz