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Participant Information Sheet

Measuring the effects of vaping on the lungs

Lead Researcher: Dr Kelly Burrowes

Study Site: Te Whatu Ora Te Toka Tumai & the University of Auckland

Contact phone number: (09) 9232748

Ethics committee ref.: **2024 EXP 19635** (approved 23rd February 2024 for a period of three years).

You are invited to take part in a study aiming to look for any effects of vaping on the lungs. 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 pull out of the study at any time.

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. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 8 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

Voluntary Participation and Withdrawal From This Study

Participation is completely voluntary, and you may refuse to participate or withdraw your consent up to 1 month after your first appointment without giving a reason. You have the right to withdraw from participation at any time during the study appointments. Information collected up until your withdrawal from the study will continue to be used and included in the study.

What is the purpose of the study?

Electronic cigarettes or vapes have only been widely available for about 20 years and only for around 5 years in New Zealand. Therefore, there is still not enough known about the effect that vaping might have on the lungs. One potential effect of vaping is that it can cause inflammation. This is our body's normal response to something foreign entering the body. If inflammation occurs over a long period of time, there is a chance it could change what the lung tissue looks like. In this study, we want to see if this is the case by measuring markers of inflammation and lung tissue structure.

How is the study designed?

We are aiming to recruit up to 35 healthy vaping participants for our study. Participation in this study will involve two clinical visits (described below) and the completion of an online questionnaire. During one clinical visit will involve a CT scan of your lungs. The other, will involve measuring your lung function and collecting some sputum from your lungs. Further details are provided below.

Who can take part in the study?

We are inviting healthy volunteers between the ages of 18-45 years old who currently vape and have vaped for at least one year. You are not eligible to participate in this study if you have a history of lung disease, including asthma, are a current or long-term ex-smoker (of conventional cigarettes) or if you are or may be pregnant.

What will my participation in the study involve?

This study will include the following three activities:

1. You will need to complete an online questionnaire about yourself and your vaping use, this should only take 5 minutes of your time.
2. You will need to attend an appointment at Greenlane Clinical Centre where you will have your lung function measured and a procedure to induce and collect your sputum, this appointment could take around 1-1.5 hours.
3. You will need to attend a radiology clinic (an Astra Radiology or Auckland Radiology Group clinic near you) to have a CT scan of your lungs, this appointment should take about 30 minutes.

Lung function measurements: These measurements will be taken by a qualified healthcare worked at Greenlane Clinical Centre. You will be asked to perform a series of breathing maneuvers to enable measurement of how well your lungs are working.

The induced sputum procedure: During this part of your appointment, you will need to inhale some saline spray to loosen sputum within your lungs. You will then need to cough and spit out some sputum into a container. This procedure will be performed at Greenlane Clinical Centre via a research nurse.

CT scan procedure: For the CT scan, you will be required to lie on your back and follow the breath hold instructions from the radiographer. The appointment will take about 30 minutes, but most of this time will be spent getting ready for the scan. The actual time inside the CT scanner should only be a few minutes.

What will happen to my sputum samples?

We will deidentify your sputum sample. This means that, while we will collect information from you that will be able to identify you, this will not be known by any of the research team (except for the lead researcher, Dr Burrowes). Instead, your sample will be given a study number that does not include any of your identifiable information.

Your sputum samples will be collected at the Greenlane Clinical Center by a registered nurse. Samples will then be sent to the Faculty of Medical and Health Sciences at the University of Auckland for analysis. Samples will be disposed of after analysis (using established guidelines

for discarding biohazard waste) and no DNA (genetic) material will be extracted or stored from your sample. A Karakia can be available at time of tissue destruction if requested. You have the right to withdraw your sample up to 1 month after it was collected. To withdraw your sample, you will need to contact Dr Burrowes (see contact details at the end of this information sheet).

You may hold beliefs about a sacred and shared value of all or any tissue samples removed. The cultural issues associated with storing your tissue should be discussed with your family/ whānau as appropriate. Samples will not be sent overseas or shared anywhere else. There are 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 before participating in research where this occurs. However, it is acknowledged that individuals have the right to choose.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

There are some potential minor risks if you do decide to be part of our study, please read the sections below and ask any questions that you may have.

Detection of Unexpected Abnormalities
There is a small chance we may discover a medical condition that you did not know about. If this happens, you will be informed of this and will be advised to consult your general practitioner. You should be aware that once you have been informed that a clinical abnormality has been detected this could affect your ability to obtain insurance whether you take the matter further or not. If a participant does not wish to be advised of such findings, then it is our policy to exclude them from taking part.

Exposure to Radiation during CT imaging
Participants will be exposed to a low dose of radiation during the CT scan. The radiation from low-dose CT scans is about 14 times that of an x-ray and delivers about half of the radiation exposure that an average person would usually receive in a year. Having more than one CT scan may slightly increase a participant's risk of cancer, however, at the relatively low doses of radiation used, the risk of developing cancer from a CT scan is so small that it is difficult to measure it.

Risk of bronchospasm during induced sputum
When we are collecting your sputum sample, there is a small risk that saline inhalation may cause your airways to narrow. This procedure will be performed by an experienced nurse, and we will have safety measures in place. If you develop a wheeze during the procedure, you will have your peak flow measured by breathing into a measurement device and if your airways do appear to be narrowed, you will be offered two puffs of salbutamol, which is a drug that will relax your airways.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You will benefit by participating in this study by having your lung health checked via CT and pulmonary function tests. We will also be able to see if there is evidence of inflammation in your lungs. The wider benefit of participating in this study is that you will be contributing to new knowledge to inform our understanding of the health effects of vaping.

WILL ANY COSTS BE REIMBURSED?

You will not incur any costs if you decide to be part of the study. We will offer you a $50 voucher after completing the study to compensate you for your participation in this study. We can also arrange to cover the cost of parking and transportation if needed.

WHAT IF SOMETHING GOES WRONG?

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.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study the staff at clinical sites (radiographer and nurses) and researchers from the Auckland Bioengineering Institute will record information about you and your study participation. This includes the results of any study assessments, this includes the CT scan of your lungs, your lung function, and your sputum samples and the things found in this sample. If needed, information from your hospital records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only Dr Burrowes and the clinical staff (at Greenlane Clinical Centre and the Radiology clinic) will have access to your identifiable information.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by researchers at the Auckland Bioengineering Institute. Instead, you will be identified by a code. Dr Burrowes will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The following groups may have access to your coded information:

- Researchers at the University of Auckland, for the purposes of this study (this may include approximately 10 people).
- Regulatory or other governmental agencies worldwide.

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Future Research Using Your Information.

[If you agree], your coded information may be used for future research related to understanding the health effects of vaping. Consent for this future use is agreed by signing the consent for this study.

This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your information may be shared widely with other

researchers or companies. Your information may also be added to information from other studies, to form much larger sets of data.

You will not get reports or other information about any research that is done using your information.

Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your information has been shared for future research.

Security and Storage of Your Information.

Your identifiable information is held at Auckland Bioengineering Institute during the study. After the study it will be transferred to a secure archiving site and stored for at least 10 years, then destroyed. All storage will comply with local and/or international data security guidelines.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

If you have any questions about the collection and use of information about you, you should ask Dr Burrowes.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing Dr Burrowes.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

Māori Data Sovereignty.

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study. To help protect this taonga:

- We have consulted with Iwi United Engaged about the collection, ownership, and use of study data.
- We allow Māori organisations to access de-identified study data, for uses that may benefit Māori.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

If you do decide you no longer want to participate in this study, you should contact Dr Burrowes (contact details below). Any collected data will be destroyed as long as it is within one month of the data collection. If we have already collected your sputum sample, we will dispose of your sample using standard protocol.

CAN I FIND OUT THE RESULTS OF THE STUDY?

Participants will be provided with a plain English summary of study results, if requested, roughly 12 months after the study date.

WHO IS FUNDING THE STUDY?

The study is funded by a James Cook Research Fellowship, administered by the Royal Society Te Apārangi on behalf of the New Zealand Government.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Central HDEC has approved this study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Dr Kelly Burrowes
Auckland Bioengineering Institute
University of Auckland
Email: k.burrowes@auckland.ac.nz
Ph: 09 923 2748

If 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@advocacy.org.nz
Website:	https://www.advocacy.org.nz/

For Māori cultural support please contact:

The administrator for He Kamaka Waiora (Māori Health Team)
Phone: 09 486 8324 ext 2324

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

Email:	hdecs@health.govt.nz
Phone:	0800 400 569 (Ministry of Health general enquiries)

Consent Form

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Please tick to indicate you consent to the following

I have read the Participant Information Sheet, or have had it read to me in a language I understand, and I fully comprehend what it says.		
I have been given sufficient time to consider whether or not to participate in this study.		
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.		
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.		
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.		
I consent to the research staff collecting and processing my information, including information about my health.		
I consent to my information being sent overseas.		
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.		
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.	Yes ☐	No ☐
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.		
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.		
I understand the compensation provisions in case of injury during the study.		
I know who to contact if I have any questions about the study in general.		

I understand my responsibilities as a study participant.

I wish to receive a summary of the results from the study. Yes ☐ No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date: