

Participant Information Sheet

CENIC-NZ



Building 507, Level 1
28 Park Ave,
Grafton, Auckland, New Zealand
T 0800 367 644

Study Title: CENIC II New Zealand Supplement. Perceptions, Concerns, Needs and Intentions Related to Reducing Nicotine in Combusted Tobacco

Sponsor: Wake Forest University School of Medicine, USA (NIH Grant)

Lead Investigator NZ: Professor Chris Bullen

Wake Forest University School of Medicine Investigators: Professor Eric Donny and A/Professor Rachel Denlinger-Apte

Study Contact Number: 0800367644

Ethics Committee Reference Number: 2022 EXP 12747

You are invited to take part in a study to share your whakaaro/thoughts, concerns and needs as a person who smokes tobacco cigarettes, about New Zealand's Smokefree Aotearoa 2025 Action Plan.

Whether or not you take part is your choice. If you don't want to take part, you don't need to give a reason. 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 will happen after the study ends.

You don't have to decide today if you wish to participate in this study. Before you decide, feel free to talk about the study with your whānau, family, friends, or the research team or your healthcare providers such as your GP.

If you agree to take part in this study, you will be asked to give consent online. We will then send you an email confirming your enrolment in the study and a copy of the Participant Information Sheet and the Consent Form to keep.

This document is 9 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

What is the purpose of this study?

This study is being undertaken by researchers at the University of Auckland and Wake Forest University School of Medicine in USA. Professor Chris Bullen is the lead investigator of this study in New Zealand. Professor Bullen is a health researcher based at a research centre called the National Institute for Health Innovation (NIHI), in the School of Population Health, University of Auckland, Auckland, New Zealand.

Professor Eric Donny, Wake Forest University School of Medicine USA, is a researcher with a special interest in evaluating new nicotine standards for cigarettes and has obtained a grant from the National Institute for Health (NIH) to complete this study.

For this study we will establish a panel of people who smoke to follow over time as the Smokefree Aotearoa 2025 Action Plan is put in place. We want to understand their views around smoking tobacco cigarettes as the NZ government plans to change its policies around tobacco.

We will gather the views of people who take part through a series of short online surveys and for participants who are willing, an additional one to one telephone interview and/or an in person visit.

The findings from this study will be used to inform the New Zealand government's tobacco policy processes, the US Food and Drug Administration's Comprehensive Plan for Tobacco and Nicotine Regulations and help plan for a new study around the impact of low nicotine tobacco in New Zealand

How is this study designed

This study will run from June 2022 to approximately February 2023. In the initial phase, we will ask people to join through Horizon Research Limited, based in Auckland, a research company that specialises in online surveys. Later, we will also use social media and direct advertising to let people know about joining the study.

First, you will answer a few questions to help us know if you can take part in the study.

If you agree to take part, you will be invited to join the "Opinions on Smoking Panel" which has 4 different smoking groups. We will continue to seek people to take part until we have 150 participants in each of these groups.

Each participant will be asked to complete up to 6 online surveys through to approximately February 2023

We will also invite up to 72 people from the panel to participate in a one-to-one phone interview and up to 50 people to take part in an in-person visit which includes an optional saliva test

All people who complete Survey 2 will be invited to provide a saliva/hūare sample (unless one has been provided during an in-person visit already) to be stored in freezers at the University of Auckland for the research team to test for tobacco or nicotine use at a later date. No other tests will be done on the provided saliva.

If we obtain further funding, we hope to retain the same panel of people for further surveys beyond February 2023. We will inform participants who complete Survey 4 about future research opportunities.

Who can take part in the study?

People who meet the following requirements can take part in the study:

- Aged 18 years and over
- Use cigarettes or other smoked tobacco products daily or almost daily

- Willing to complete up to six brief surveys online
- Able to speak and understand English
- A New Zealand citizen or permanent resident

What will my participation in the study involve?

If you are interested in taking part, you will be asked to provide online consent before completing the first survey. Survey 1a asks about your ethnicity, nicotine and tobacco use, use of alcohol and cannabis and your wellbeing. The next Surveys (1b, 2, 3 and 4) ask questions about your thoughts on smoking and the Smokefree Aotearoa 2025 Action Plan. These online surveys should take you no more than 10 minutes to complete.

Interviews

We will invite 72 people who complete Survey 1b to participate in a telephone interview with University of Auckland researchers (taking about 30-45 minutes) to discuss the government's Smokefree Aotearoa 2025 Action Plan. The interview results will be used to help us know the right questions to ask in Survey 2 onwards.

You will be asked for consent to take part at the beginning of the interview. Interviews will be conducted by staff from NIHI located at University of Auckland who are matched to the people in the panel groups.

Your conversation will be audio-recorded and then transcribed, word-for-word, after the interview to be analysed by the researchers. For your protection, your name and any identifying information about you or other people will be excluded from the transcript.

The following graphic shows how the study processes will take place:



In person visit sub-study

All people who complete Survey 1b will be asked if they would be willing to complete an in-person visit (about 45 minutes) at a place of their choice e.g., home, work or community venue. This interview will be completed by a team of investigators from both the University of Auckland and Wake Forest University School of Medicine, to see how feasible it is to collect in-person data and

saliva samples for a future study. There will be 2 brief questionnaires, one on the use of tobacco products and vaping and one on participant satisfaction of the interview. Measures will include exhaled breathe carbon monoxide, heart rate, blood pressure, height and weight, respiratory function (i.e., spirometry), and the collection of a saliva sample if you are willing. A photo of smoked tobacco products currently used will also be taken. At this stage it is planned that only people in the greater Auckland and other regions in the North Island of New Zealand will be asked to participate.

Consent for the in-person visit will be included in the first questionnaire.

Saliva/hūare collection sub-study

As noted earlier, all the people who complete Survey 2 will be asked if they are willing to provide a saliva/hūare sample (unless one has been provided as part of an in-person visit already) for the University of Auckland researchers to test for biochemical markers that indicate recent use of tobacco and nicotine. People agreeing to give a sample will be sent a saliva collection kit to use and send their sample back to us by courier. The samples will be stored in a freezer at -80C at the University of Auckland for future analysis for biochemical markers of use of nicotine and tobacco products such as smoking cigarettes, NRT or vapes. Two biomarkers are currently planned: Nicotine metabolite ratio (NMR) and Cotinine (a breakdown product of nicotine). No other tests will be done on the saliva/hūare.

Your saliva/hūare sample will be kept safely in the freezer for 24 months and then disposed of according to University of Auckland protocols.

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. 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.

If you wish, karakia will be recited at the time we dispose of the samples. We cannot return your sample to you, due to the chance of an active infectious agent being present. No samples will be sent overseas.

Consent for the saliva/hūare sample will be included in Survey 2.

What are the risks and benefits of this study?

There are no immediate direct benefits to you for participating in this study, however your participation will help us understand people's views on the Smokefree Aotearoa 2025 Action Plan. This information is likely to assist the decisions made by governments in New Zealand and worldwide about regulating tobacco products.

We do not anticipate any risks with this study. However, for some people, the questions around smoking, alcohol or mental health can be upsetting. If you experience *mamae* / distress, there is free and confidential support available through the following help lines:

- National helpline. Free call or text 1737 any time for support from a trained counsellor
- Quitline on 0800 778 778 for support and advice about your smoking
- Alcohol Drug Helpline' on 0800 787 797, if you are concerned about your own or some else's alcohol use

What will happen to my information?

During this study, the research staff will record information about you and your study participation. This includes the answers to the survey/interview questions. 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).

The following groups of people may have access to your identifiable information:

- Approved research staff administering surveys and interviews, processing saliva samples and deidentifying the information
- Laboratory staff, to process your saliva tests, if you are in the saliva collection group
- The ethics committees or government agencies from New Zealand or overseas, if the study is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.
- Rarely, it may be necessary for Professor Bullen to share your information with other people. For example, if there is a serious threat to public health or safety, or to the life or health of you or another person, or if the information is required in certain legal situations.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report or publication generated by NIHI or any information sent to Wake Forest University School of Medicine investigators. Instead, you will be identified by a code. The research team 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:

- The research team at NIHI and Wake Forest University School of Medicine USA, for the purposes of this study
- Regulatory or other governmental agencies in NZ and USA

De-identified results data will be sent overseas to the following group:

- The research team at Wake Forest University School of Medicine, USA for the purposes of additional statistical analyses. Transfers of data to Wake Forest University School of Medicine will be under terms that require comparable protections for the data to those under New Zealand privacy laws.

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

Security and Storage of Your Information

Your identifiable information is held on computer servers in New Zealand operated by the University of Auckland and Horizon Research Limited during the study. De-identified information sent to Wake Forest University is held on computer servers located in the US.

Your coded study information will be kept in a secure, cloud-based storage facility for at least 10 years. All storage will comply with local and/or international data security guidelines.

Risks

Although efforts will be made to protect your privacy, the 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 may ask us to confirm what personal information we hold about you, and request access to and/or correction of that information. In some circumstances we may be unable to provide the access or make the correction, for example, where the information has been collected as part of the study information and is important that it reflects the information originally provided at that time

If you have any questions about the collection and use of information about you, you should ask Professor Chris Bullen, (contact details on page 8).

Rights to Withdraw Your Information

You may withdraw your consent for the collection and use of your information at any time, by contacting Professor Chris Bullen in writing (contact details on page 8). At this time your study participation will end, and the study team will stop collecting information from you.

If you agree, information and sample results collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

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 Dr George Laking (Te Whakatohea), from the University of Auckland, about the collection, ownership, and use of study data from Māori participants.
- Māori organisations will be able to access de-identified study data, for uses that may benefit Māori.
- Māori health researchers will review the study results and the interpretation of them before the results are released to others in publications or presentations.

Can I find out the results of the study?

Participants can request a summary of the study results once the final study report is available (this can take up to nine months after the end of the study).

Who is Funding the study?

This study is funded by a USA National Institutes of Health (NIH) grant awarded to Professor Eric Donny at Wake Forest University School of Medicine.

Will any costs be reimbursed?

To recognise participation in this research, participants will be reimbursed in the following ways

- \$100 prize cash draw every month for participants completing the surveys
- Extra \$200 prize cash draw at the end of the study for those who complete all the surveys
- \$50 for those participating in the one-to-one phone interviews and/or study visits.
- \$20 for participants providing a saliva/hūare sample

Who has approved this 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 Health and Disability Ethics Committee 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:

Name: Professor Chris Bullen
Phone: 021415267
Email: c.bullen@auckland.ac.nz

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 Maori cultural support, please contact:

Name : Dr George Laking (Te Whakatohea)
Email: g.laking@auckland.ac.nz

For Pasifika cultural support, please contact:

Name : Associate Professor Vili Nosa
Email: v.nosa@auckland.ac.nz

Consent Form (online)

CENIC-NZ



NIHI
The National Institute
for Health Innovation



By completing this online consent form I agree that:

I have read, or have had read to me, and I understand the information provided in Participant Information Sheet.		
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, whānau/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 employment or medical care. 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 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 that de-identified results data once analysed in New Zealand will be sent overseas to Wake Forest University School of Medicine, USA.		
I understand that information may be shared with other studies or registers, or in reports for agencies who are reviewing the reduction of nicotine in tobacco products, but that no information that identifies me personally will be used.		
I know who to contact if I have any questions about the study in general.		
Declaration by participant online in Survey 1: I consent to take part in this study		
The following questions will be included in the surveys as indicated		
Survey 1b I agree to take part in a one-to-one phone interview (30-45 mins) if selected	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Survey 1b I am willing to be contacted about taking part in an in-person visit (45 mins) if selected	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Survey 2 I agree to providing a saliva/hūare sample for analysis of exposure to nicotine and tobacco. The sample will be stored at the University of Auckland for up to 24 months. Analyses will be limited to biomarkers of exposure to nicotine and tobacco. I wish to have a karakia at the time my saliva/hūare sample is destroyed	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Survey 4 I wish to receive a summary of the results from the study.	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Survey 4 If additional funding is received, I agree to be contacted to see if I am willing to take part in further research.	Yes <input type="checkbox"/>	No <input type="checkbox"/>