

Participant Information Sheet

CENIC-NZ Surveys



Waipapa
Taumata Rau
University
of Auckland

Building 505, Level 2
85 Park Road,
Grafton, Auckland,
New Zealand

Study Title: Assessing nicotine and tobacco use behavior in New Zealand

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

Lead Investigator NZ: Professor Chris Bullen (University of Auckland)

Co-investigators: Professor Natalie Walker (Flinders University, Australia), Associate Professor George Laking (University of Auckland), Associate Professor Vili Nosa (University of Auckland), Professor Rachel Denlinger-Apte (Wake Forest University School of Medicine, USA), Professor Eric Donny (Wake Forest University School of Medicine, USA), Dr Dorothy Hatsukami (University of Minnesota, USA), Professor Joseph Koopmeiners (University of Minnesota, USA), Dr Michael Chaiton (University of Toronto, Canada).

Study Contact: CENIC-NZ-Surveys@auckland.ac.nz or 027-304 2328

Ethics Committee Reference Number: AH28284

You are invited to take part in a study which will use surveys to understand opinions, intentions, and behaviours related to nicotine and tobacco over time.

This Participant Information Sheet will explain the study in more detail and help you decide if you would like to take part. It sets out why we are doing the study, what your participation would involve, possible risks and benefits, and what will happen after the study ends.

Note:

- 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.
- 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 your consent online after reading this participant information sheet and consent form. You can download a copy of this document for your reference or email the study team at any time to retrieve a copy. You will also be asked for a digital signature to indicate that you consent to continue and will need to provide your contact details (a valid phone number, email and home address).

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

Who are the people running this study?

The Research Team consists of:

- Professor Chris Bullen, who is the lead investigator of this study in New Zealand. Professor Bullen is a health researcher based at the School of Population Health, University of Auckland, Auckland, New Zealand.
- Trained research team members at the School of Population Health, Auckland, New Zealand.
- Professors Rachel Denlinger-Apte and Eric Donny are researchers at Wake Forest University School of Medicine in the U.S. They have a special interest in evaluating new policies affecting the amount of nicotine in cigarettes and have obtained a grant from the U.S. National Institute for Health to undertake this study in New Zealand.

What is the purpose of this study?

For this study, we will create a panel of people who smoke and, over the next three years, invite them to answer short online surveys to understand whether current smoking behaviour, interest in quitting smoking, and aspects of health and wellbeing change, as the tobacco and nicotine marketplace evolve in NZ.

The findings from this study will be reported to the tobacco policy team in New Zealand Ministry of Health and HealthNZ to help them evaluate the impact of tobacco-related policies and changes to the nicotine and tobacco marketplace. The findings from this study may also inform future policy decisions made by the U.S. Food and Drug Administration's Center for Tobacco Products. Your personal information is kept confidential, and information that identifies you will not be included in any published report / publication or any information.

How is this study designed?

People who are eligible to take part will complete one longer annual online survey and up to two short online surveys every three months, until the end of 2027.

Who can take part in the study?

People who meet the following requirements may be asked to take part in the study:

1. People able to read and understand the study materials (surveys and this information sheet) written in English, or those with translational support to complete each survey.
2. People who are aged 18 years or older.
3. People living in New Zealand as a citizen or permanent resident.
4. People who currently smoke tobacco.
5. People willing to complete the annual survey and up to 2 surveys every 3 months through 2027.

What will my participation in the study involve?

Am I eligible? If you are interested, after providing consent, you can complete a brief Screening Survey to see if you are eligible to join the long-term study. The Screening Survey contains two parts; first, your contact details and some questions about your ethnicity, age, education level, alcohol and cannabis use, health and wellbeing and some questions to assess your eligibility to be part of the longer study. Please note, we may contact you to ensure we have your correct contact information. You can complete the Screening Questionnaire only once and if shows you are eligible, you will receive more surveys to complete.

If you are eligible: Up to 1500 people who are eligible will receive surveys to complete over time (up to 2 surveys per 3 months through and including 2027).

Each survey may ask questions on a variety of topics, including but not limited to, the following:

- Cigarette and smoked tobacco products
- Nicotine vaping products
- Oral nicotine products
- Oral tobacco products
- Heated Tobacco Products
- Nicotine replacement therapies (NRT)
- Illicit nicotine products, nicotine product tampering, and homegrown tobacco
- Reactions to potential and actual changes in tobacco policy and the tobacco and nicotine marketplace
- Alcohol, cannabis, and other drug use
- Health and well-being.

Some questions may be asked in multiple surveys, while other questions may only be asked once. Before each survey, we will tell you about the topics we will be asking you about so you can decide if you want to complete the survey.

All surveys can be completed online and will take between 5 and 30 minutes to complete.

Your responses will be saved in a secure, online database called REDCap at the University of Auckland. Data storage servers are in NZ.

You will have two weeks to complete each new survey. Everyone will receive the surveys at the same time and then we will schedule the survey to close after two weeks. You will receive reminder emails to complete the survey during the two weeks.

You will also be invited to learn more about other related research opportunities (such as in-person visits or interviews).

What are the risks and benefits of this study?

There are no immediate, direct benefits for participating in this study, however your participation will help us understand how changes in the nicotine and tobacco marketplace in NZ, and any related policy changes, impact opinions, intentions, and behaviours. This information will be valuable to New Zealand government and others around the world.

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 questions. You cannot take part in this study if you do not consent to the collection of this information. Information collected in the Screening Survey will be held securely for all participants; including those who are not eligible to continue to receive further surveys.

Identifiable Information

Identifiable information is considered any data that could identify you (e.g. your name, date of birth, or address). The following groups of people may have access to any identifiable information you provide when undergoing screening to join the study, when providing consent, and when completing the study surveys:

- Approved research staff at UOA administering surveys and deidentifying the information.
- The ethics committees or government agencies from New Zealand or overseas if the study is audited. Audits are done to make sure that participants and their data are protected, the study is run properly, and the data collected are 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 published report / publication or any information sent to Wake Forest University School of Medicine researchers. Instead, you will be identified by a code. The approved research team at UOA, will keep a list linking your code with your name (on the REDCap database), so that you can be identified by your coded data if needed.

The following groups may have access to your de-identified (coded) information:

- The research team and supporting personnel at the UOA, and including the co-investigators working on the study.
- Regulatory or other government agencies in NZ and USA.

De-identified results data will be sent overseas to the study co-investigators for additional statistical analysis. Transfers of data to overseas co-investigators will be under terms that require comparable protections for the data to those under New Zealand privacy law, and Māori and Pacific Data Sovereignty principles.

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 securely on a REDCap database, secure research drives, virtual machines, and cloud-based storage facilities (such as SharePoint™ and Microsoft Applications™), on computer servers operated by the University of Auckland during the study. De-identified results sent to overseas co-investigators are held on secure computer servers located in the designated country.

All information, including Screening Survey responses from eligible and ineligible participants, is held securely for at least 10 years. This information is used to describe the groups of people that enrolled and participated in the study. 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 de-identified 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 it 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 the study team CENIC-NZ-Surveys@auckland.ac.nz. At this time 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 and Pacific Data Sovereignty

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

- We have consulted with Associate Professor George Laking (Te Whakatōhea) and Associate Professor Vili Nosa (Niuean) from the University of Auckland, about the collection, ownership, and use of study data from Māori and Pacific participants.
- Māori and Pacific organisations will be able to access de-identified study data, for uses that may benefit Māori or Pacific peoples.
- Māori and Pacific health researchers will review the study results and comment on the interpretation of the results before any results are released to others, such as in publications (e.g. medical journal articles) or presentations at conferences.

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 in September 2027).

Who is Funding the study?

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

Will any costs be reimbursed?

To recognise your participation in this research, you will be reimbursed in the following ways:

- During the recruitment period and in the month you complete the screening, you will be entered in a \$100 prize draw (NZ supermarket gift vouchers) with others who completed the screening survey that same month. One person will be selected at random and will be awarded the prize (vouchers).
- Eligible participants will be compensated according to the estimated average length of time required to complete each survey, and as per the table below. Participants will be informed of

the estimated average length of time to complete the survey and compensation amount at the start of each survey.

Predetermined estimated average length of completion	Compensation amount
1-10 minutes	\$5 NZD (NZ Supermarket voucher)
11-20 minutes	\$10 NZD (NZ Supermarket voucher)
21-30 minutes	\$20 NZD (NZ Supermarket voucher)

- Eligible participants will receive an extra \$20 (NZ supermarket voucher) completion bonus for completing at least 75% of the online surveys administered in a 12-month period (example: completing six out of eight surveys in a 12-month period). Please note, these supermarket vouchers can only be used in stores throughout New Zealand.

Who has approved this study?

This study has been approved by an independent group of people called the Auckland Health Research Ethics Committee (AHREC) who check that studies meet established ethical standards. The AHREC 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 Māori cultural support, please contact:

Name : George Laking (Te Whakatōhea)

Email: g.laking@auckland.ac.nz

For Pasifika cultural support, please contact:

Name : Associate Professor Vili Nosa (Niuean)

Email: v.nosa@auckland.ac.nz

AHREC Chair contact details:

For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at 373 7599 ext 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

Approved by the Auckland Health Research Ethics Committee for three years on from

08/10/2024, Reference number **AH28284**

Consent Form (online) CENIC-NZ Surveys	 Waipapa Taumata Rau University of Auckland
--	---

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 this 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 access to an electronic or hard 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 exported public reports on this study.
I understand that de-identified results, once analysed in New Zealand, will be sent overseas to study co-investigators.
I understand that information may be shared with other studies or registers, or in reports but that no information that identifies me personally will be used.
I understand that I may be contacted and invited to other studies.
I understand that a brief overview of the content of each survey will be shared at the start of each survey.
I know who to contact if I have any questions about the study in general.

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

If you agree to join the study, please select “Yes” on the online registration form, and provide your digital signature to show that you have read this form and consent to join the study.

AHREC Chair contact details:

For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at 373 7599 ext 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

Approved by the Auckland Health Research Ethics Committee for three years on from

08/10/2024, Reference number **AH28284**