

# Participant Information Sheet



**MEDICAL AND  
HEALTH SCIENCES**  
SCHOOL OF PHARMACY

## Exploration of inherited propensity for codeine misuse and dependence

Lead: Dr Rhys Ponton

Study Site: School of Pharmacy, University of Auckland

Contact phone number: 09 3737599 Extn. 87084

Ethics committee reference: 2022 EXP 12248

You are invited to take part in a study that looks at the misuse and dependence of the pain relieving drug, codeine. 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 in this study is voluntary. You are free to decline to participate.

Participation, non-participation, or withdrawal will not affect your relationship with the University of Auckland or any healthcare services you access.

You can withdraw from the research at any time without experiencing any disadvantage, and your data will be removed from the study unless it has been de-identified.

## WHAT IS THE PURPOSE OF THE STUDY?

This research looks at the misuse of, and dependence on, the drug codeine. We are trying to establish whether some people are more likely to develop these issues when taking the drug.

The study will look at how the inheritance of different types of an enzyme that activates the codeine in the body relate to misuse or dependence in people. We believe that people who activate codeine too rapidly are more likely to develop these problems. By looking at the enzyme types present in people who misuse or are dependent on codeine, we may be able to determine if this is the case.

A better understanding of this enzyme system and codeine misuse will potentially enable safer use of codeine in medical care and reduce the risks of people misusing or becoming dependent upon it.

## HOW IS THE STUDY DESIGNED?

We are looking for up to **twenty** people in New Zealand to participate in the research.

The study involves two stages. The first stage is an interview to discuss codeine use, including the reasons why it was first taken or prescribed, then how this use developed into misuse and dependence. The second stage involves participants providing a saliva sample to allow us to test for which type of enzyme (fast, slow or normal) that you have inherited.

## WHO CAN TAKE PART IN THE STUDY?

You can participate in this research study if you:

- Are 18 years of age or over
- Started regular opioid use with codeine
- Codeine is your primary opioid of use
- Are happy to talk to a researcher about your codeine use, via videolink or telephone
- Are willing to provide a saliva sample for gene analysis

## WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

If you choose to participate in this study, you can do so from your home.

It will involve three stages, once you get in contact with us to express an interest in participating:

1. A short telephone conversation with a researcher to confirm you are suitable to take part in the research
2. An interview that will be held either through your computer (using video) or by telephone if you do not have access to a computer. This interview will take a maximum of 30 minutes.
3. Providing a saliva sample into a special container. This will usually take about 5 minutes of your time. You won't be able to eat, drink, smoke, vape or chew gum for 30 minutes before collecting your saliva. The container will be sent to you at

home and then sent back by you in the post, there will be no need to go anywhere and no need to attend a clinic. The postal costs will be covered by us.

You will not need to come to the University. You will not need to discuss participation with your codeine prescriber (if you have one), but you may do so if you wish. The research team will not contact your prescriber or share any information or results with them.

### WHAT WILL HAPPEN TO MY SALIVA SAMPLES?

Once you have collected your saliva sample into the collection tube provided, you will need to place the tube into the pre-paid envelope provided and then place it in the mail. The saliva samples will be delivered to the University of Auckland. We will then give your sample a unique code. The coded sample will be then stored in a secure laboratory location at the Faculty of Medical and Health Sciences prior to processing and analysis for the gene which makes the enzyme important for codeine activation. This gene is called *CYP2D6*. It is planned that this analysis will take place in Auckland. The saliva will be consumed as part of the preparation of DNA for analysis of this gene.

No samples will be sent overseas and the genetic information will only be used for this research project. This genetic information is confidential and will not be disclosed, stored, or used in any way without your informed consent.

You may hold beliefs about a sacred and shared value of bodily samples and genetic material. No samples from this study will be sent overseas or stored beyond the period of this project: any samples remaining after completion of the final data analysis will be destroyed. The cultural issues associated with donating this sample 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 decide to withdraw from the study, please notify a member of the research team and the saliva sample or the prepared DNA will be destroyed. A karakia upon destruction of your saliva sample can be held if you wish, please discuss this option with the researcher during the interview. Alternatively, if you wish, you can have the saliva/DNA sample returned to you.

### WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

If you experience concern following the discussion of your drug use, the research team will be able to advise on healthcare providers who can provide further care.

### WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There will be no direct benefit to you for participating in this study. Information learnt from this study may help to develop in the future a predictive test to determine which patients may be at most risk of developing dependence on codeine.

The results of the study will be published in a scientific journal once all laboratory studies have been completed. You may request to receive a lay summary of the results of the research for yourself or a nominated whānau/support person when they become available.

### **WILL ANY COSTS BE REIMBURSED?**

There will be no cost to you to participate in this study.

A \$50 koha (thank you) gift card will be offered to all participants who complete the study. This will be sent to participants following the interview and once the saliva sample is returned.

### **WHAT WILL HAPPEN TO MY INFORMATION?**

During this study the research team staff will record information about you and your study participation. This includes the results of any study assessments and information about the *CYP2D6* gene.

#### Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only the research team will have access to your identifiable information. The research team are Dr Rhys Ponton, Associate Professor Nuala Helsby and Carina Walters, who are based at the University of Auckland.

#### 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 the research team. 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 list linking the participant codes with names will be confidential and only accessible by the study investigators.

Only the research team will have access to your coded information.

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.

All data will be stored securely at the University of Auckland by the researchers. The consent forms will be stored in a locked cabinet. The digital recordings and also the data about the *CYP2D6* gene will be stored securely with password protection on a computer drive which only the research team can access.

The recorded interviews will be destroyed once transcribing is finished. Consent forms will be kept for six years and then securely destroyed. Information including transcribed interviews and data analyses will be stored indefinitely. The data we collect will be used in presentations and in publications in peer-reviewed journal papers. You will not be able to be identified in any information that is reported or published.

#### Risks

Although efforts will be made to protect your privacy, 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.

This research includes basic information such as your ethnic group, age, and gender. It also collects information about the type of *CYP2D6* activity you have (fast, slow or normal). It is possible that this research could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatise, or discriminate against members of the same groups as you.

#### 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.

You may access other study-specific information before the study is over, but this could result in you being withdrawn from the study to protect the study's scientific integrity.

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

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

#### Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information, by informing the research team.

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

If you decide to withdraw from the study, the saliva sample or the prepared DNA will be destroyed, or if you wish, you can have the saliva/DNA sample returned to you.

If you indicate on the consent form that you agree that information collected up to the point when you withdraw may continue to be processed.

### CAN I FIND OUT THE RESULTS OF THE STUDY?

Please indicate on the consent form if you wish to receive a summary of the study findings.

### WHO IS FUNDING THE STUDY?

This study is funded by the Health Research Council (HRC) of New Zealand.

### 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 Health and Disability Ethics Committee has approved this study (Ref: 2022 EXP 12248).

## 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:

*The Research Team by email: [codeinestudy@auckland.ac.nz](mailto:codeinestudy@auckland.ac.nz)*

*Dr Rhys Ponton, School of Pharmacy  
[r.ponton@auckland.ac.nz](mailto:r.ponton@auckland.ac.nz)  
09 9237084*

*Head of School - Pharmacy  
A/Prof Shane Scahill, School of Pharmacy  
[s.scahill@auckland.ac.nz](mailto:s.scahill@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](mailto:advocacy@advocacy.org.nz)  
Website: <https://www.advocacy.org.nz/>

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

Phone: 0800 4 ETHIC  
Email: [hdecs@health.govt.nz](mailto:hdecs@health.govt.nz)

### Maori Support

If you require Māori cultural support, contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 307 4949 ext 29200.

# Consent Form



## Exploration of inherited propensity for codeine misuse and dependence

**Please tick to indicate you consent to the following**

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I have read or have had read to me in my first language, and I understand the Participant Information Sheet.

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I have been given sufficient time to consider whether or not to participate in this study.

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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.

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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.

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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.

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I consent to the research staff collecting and processing my information, including information about my health.

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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. Yes  No

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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.

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I know who to contact if I have any questions about the study in general.

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I understand my responsibilities as a study participant.

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

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I consent to participate in a recorded interview which will discuss my use of codeine

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I consent for genetic testing of my saliva sample for the gene which is important in activation of codeine

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If there is any unused portion of my saliva or DNA, I would like this returned to me rather than being destroyed Yes  No

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**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: \_\_\_\_\_