You are invited to take part in a study on the effects of taking another medication to help prevent acute attacks of gout when commencing urate lowering therapy. 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 5 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

**WHAT IS THE PURPOSE OF THE STUDY?**

Gout is a common and challenging problem. Gout is particularly common in New Zealand. High levels of uric acid in the blood are the main cause of gout.

For gout to be controlled uric acid levels need to be below 0.36mmol/l or 0.30mmol/l for people who have more severe disease. If the target level is achieved over the long term the number of attacks of gout will reduce and stop and tophi will dissolve.

Long-term urate lowering therapy is required to reduce serum urate. However, commencement and increasing the dose of urate lowering therapy can be associated with gout attacks. It is therefore recommended that patients receive another medication to protect against acute attacks when commencing urate lowering therapy. Urate-lowering medications such as allopurinol are now started at low doses and increased slowly. This approach may mean that not everyone who starts allopurinol will need another medication to prevent acute attacks. Low-dose colchicine is one medication recommended for preventing gout flares. We want to find out if low dose colchicine reduces gout flares compared to a placebo when starting allopurinol.

This study has been funded by the Health Research Council of New Zealand and has received ethical approval from the New Zealand Health and Disability Ethics Committee.
WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You are invited to participate in this study because you have gout and you are going to start allopurinol to reduce your uric acid levels. During the study you will continue all your usual medications.

IF you agree to participate in this study the study coordinator will see you and

1. You will be asked to fill out a questionnaire about your gout (e.g. how old you were when you had your first attack, how many attacks you have had in the last year and whether you have any other medical problems)

2. You will be provided with the study medication. This will either be colchicine or placebo capsules. You will not know which one you have been allocated and nor will the study coordinator. You will also be given a prescription for another pain relief medication to use for gout attacks if you need it. This will either be prednisone or a non-steroidal anti-inflammatory such as diclofenac or naprosyn.

3. You will be asked to have blood tests. We will test your uric acid, kidney function and the levels of allopurinol and colchicine in your blood. These tests will be done at a laboratory in Auckland or at the University of Otago. At each visit you will be asked questions such as how many attacks of gout you have had and whether you have had any side effects from allopurinol or the study drug.

4. With your consent we may also contact your family doctor, review relevant medical records or access your New Zealand Health Information Service Records so we can see how your health has been.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

It is possible that you may experience some bruising and discomfort after the blood sample is taken. The most common adverse effects of colchicine that some people experience are gastrointestinal, including nausea and diarrhoea. If you experience these please let us know. For those who receive the placebo there is a risk you will have more gout flares. We will be asking about how many gout flares you are having and provide you with a way of treating these.

WHO PAYS FOR THE STUDY?

This study is funded by the Health Research Council of New Zealand. You will be provided with a $10 petrol voucher for each visit you are required to make for the study. You will be required to pay the prescription charges for your allopurinol.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, which is unlikely, 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 ARE MY RIGHTS?

Your participation in this study is voluntary and you are free to decline to participate, or to withdraw from the research at any practicable time, without experiencing any disadvantage. If you would like to withdraw from the study at any time you can contact the research co-ordinator. Any blood samples or information that have been analysed up to that time will continue to be used.

If you wish to access the information we collect about you as part of this study we can arrange that.

We will inform you of any new information about adverse or beneficial effects related to the study that becomes available that may have an impact on your health.
All information collected as part of the study will be stored in locked offices in the University of Auckland and at the University of Otago, Christchurch. Information will also be recorded in our secure databases, but not in a form that can identify you.

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

At the end of the study you will continue your treatment as prescribed by your doctor. Your study records will be stored in a locked cabinet in the Department of Medicine/Rheumatology and stored for at least 20 years. Professor Dalbeth and Professor Stamp will be responsible for the secure storage of all data.

Overall results of the study will be available from the investigators several months after the study has been completed. This may be 12-18 months after your involvement in the study.

The blood samples collected during the study will be stored in our secure freezers. If you wish your samples to be destroyed with karakia we can arrange this.

**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, position**: Dr Anne Horne
- **Telephone number**: 09-923-9787
- **Email**: a.horne@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@hdc.org.nz

For support, talk to your whānau in the first instance. Alternatively you may contact the administrator for He Kamaka Waiora Māori Health Team on 09 486 8324 ext 2324. If you have any questions or complaints about the study, you may contact the Auckland and Waitematā District Health Boards' Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext 3204.

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

- **Phone**: 0800 4 ETHICS
- **Email**: hdecs@moh.govt.nz
Please tick to indicate you consent to the following

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet. 
Yes □ No □

I have been given sufficient time to consider whether or not to participate in this study. 
Yes □ No □

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. 
Yes □ No □

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. 
Yes □ No □

I have been given an information sheet about the risks of colchicine and have had the chance to read it and ask any questions I may have. 
Yes □ No □

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. 
Yes □ No □

I consent to the research staff collecting and processing my information, including information about my health. 
Yes □ No □

I understand that my GP or current provider will be informed about my participation in the study and of any significant abnormal results obtained during the study. 
Yes □ No □

I agree to my blood samples being sent overseas and I am aware that these samples will be disposed of using established guidelines for discarding biohazard waste. 
Yes □ No □

I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic 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.  

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 wish to receive a summary of the results from the study.  

I consent to the use of my data for future related studies, which have been given ethical approval from a New Zealand Accredited Ethics Committee  

I consent to the researchers accessing my New Zealand Health Information service records  

I consent to being contacted in the future for follow-up studies  

I wish my samples to be destroyed with Karakia

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: