

**Participant Information Sheet**

Department of Medicine

Faculty of Medical and Health Sciences, University of Auckland

25 Park Ave, Grafton, Auckland 1023, New Zealand

**Project Title:** Adherence in patients taking methotrexate for arthritis

**Name of Principal Investigator:** Dr Rachel Murdoch

**Name of Co-investigators:** Professor Nicola Dalbeth, Professor Keith Petrie

**RESEARCHER INTRODUCTION**

Our names are Dr Rachel Murdoch, Professor Nicola Dalbeth, and Professor Keith Petrie and we are doctors who are currently doing a research study within the Bone and Joint Research Group in the Faculty of Medical and Health Sciences at the University of Auckland.

**AN INVITATION**

You are invited to take part in a study to understand why people decide whether or not to take methotrexate when it is prescribed for arthritis. 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 want to take part now, but change your mind later, you can pull out of the study. It is possible that one of the researchers may have seen you previously as part of your arthritis management. Participation or non-participation in the study will have no impact on your health care.

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 whānau, friends, or healthcare providers. Please 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 Consent Form to keep.

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

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

Methotrexate is a common medication prescribed for arthritis. We would like to understand peoples’ reasons for taking or not taking methotrexate in order to understand better why people might decide not to take the medication.

**WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?**

You will be invited to attend a single research visit which can be held either in-person at the Greenlane Clinical Centre, in-person at the University of Auckland Clinical Research Centre, or remotely over Zoom according to your preference.

During the visit you will be asked demographic information such as your age, gender and ethnicity and clinical questions about your arthritis such as what type of arthritis you have and what medication you take for it. You will also complete some questionnaires with the researcher which will include questions about reasons for taking or not taking methotrexate and questions about possible side effects that you might have experienced from methotrexate.

The study visit will take up to one hour. After attending the study visit, you will receive a $50 MTA (petrol) voucher to thank you for your participation.

We do not expect your participation within this study will put you at risk of any serious adverse event.

As part of the interview, we will be collecting personal and health information from you. This may include information about your medicines and latest blood test results from your medical records. Information from your health records will only be accessed if you give us consent to do this. Only information relevant to arthritis will be accessed. You may hold beliefs about sacred and shared values of any health related data. The cultural issues associated with storing your data should be discussed with your whānau as appropriate. If you need cultural support this can be provided. Please let us know and we will arrange this for you or you can ring the number at the bottom of the participant information and consent form. Cultural support is different to knowing more about the study. In these cases we can arrange for a primary investigator to talk with you and your whānau about the study.

It is possible that participants might be emotionally affected by completing a questionnaire asking about their health and medication. If this were to happen, they will be given additional time, and the option of discontinuing.

It is unlikely that any health findings requiring follow-up will be discovered through your participation in this study. However, if any medical problems requiring follow up are found, your GP or usual healthcare provider will be informed so that they can arrange the appropriate follow-up.

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 HAPPENS AFTER THE STUDY AND WHAT HAPPENS WITH MY INFORMATION?**

During this study the researchers will record information about you and your study participation. This includes the results of the study questionnaires and relevant blood test results and pharmacy dispensing information from your hospital records. 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 may have access to your identifiable information:

* The study staff (to complete study assessments)
* Your GP if any unexpected health findings requiring follow-up are discovered in this study
* The sponsor (the University of Auckland) and its representatives, if you make a compensation claim for study-related injury. Identifiable information is required in order to assess your claim.
* The sponsor (the University of Auckland), ethics committees, or government agencies from New Zealand if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.

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 researchers. The researcher, Dr Rachel Murdoch, 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 study researchers.
* The sponsor (the University of Auckland), for the purposes of this study.
* Health, regulatory, or government authorities, to comply with legal and regulatory duties.

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 will be stored securely at the Department of Medicine at the University of Auckland during the study. After the study it will be archived securely at the University of Auckland or transferred to a secure archiving site and stored for at least 10 years, then destroyed.

All electronic data will be stored on a password protected data server at the University of Auckland accessible only to the study researchers. After 10 years all paper forms will be shredded and all electronic data will be erased. All storage will comply with local data security guidelines. No data will be sent overseas in this study. The study will take over a year to complete. If you would like to receive a summary of the results of the study, we will email you with the results of the study at the end of this time.

We plan to publish results from this study in scientific journals so that the information is freely available to other doctors, researchers and the public. The results generated from the study may be made available for use in future research. Individual participants will not be identified in any report or publication and all information about your identity will be kept strictly confidential.

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, please ask the study researchers.

**RIGHT TO WITHDRAW FROM PARTICIPATION**

Participation in this study is voluntary (your choice). You are free to decline to participate or withdraw from the research without any disadvantage to you. You do not need to give a reason to withdraw from the study. You have the right to access the information collected about you as part of the study.

If you decide after the study visit to withdraw from the study, you have the right to withdraw your collected information as long as you let us know within 2 weeks. After 2 weeks, the information collected may continue to be processed as part of the study.

**ANONYMITY AND CONFIDENTIALITY**

Your participation in this study will remain confidential. We will ensure that the information collected is protected, by assigning all data we collect from you with a study number. No information collected, which could identify you personally, will be used in any reports on this study. Your information and scans will be stored securely in electronic and paper form. Apart from the study researchers, no one else will have access to your information.

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

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

Dr Rachel Murdoch (Primary Investigator)

Telephone 09 923 4139

Email: rachel.murdoch@auckland.ac.nz

Or: Professor Nicola Dalbeth (Head of Department and Co-investigator)

Telephone 09 923 2568

Email: n.dalbeth@auckland.ac.nz

If you have any questions or concerns about your rights as a participant in this research study and want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Telephone: (NZ wide) 0800 555 050
Free Fax (NZ wide): 0800 2787 7678 (0800 2 SUPPORT)
Email (NZ wide): advocacy@hdc.org.nz

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

For Māori cultural support, consider speaking with your whānau in the first instance. Alternatively you may wish contact the administrator for He Kāmaka Waiora (Māori Health Team) on: 09 486 8324 ext 42324.

**CONSENT FORM**

Department of Medicine

Faculty of Medical and Health Sciences, University of Auckland

25 Park Ave, Grafton, Auckland 1023, New Zealand

**This form will be held for a period of 6 years**

**Project Title:** Methotrexate and adherence

**Name of Principal Investigator:** Dr Rachel Murdoch

**Name of Co-investigators:** Professor Nicola Dalbeth, Professor Keith Petrie

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| I have read and I understand the 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 medical care. |
| I consent to the research staff collecting and processing my information, including information about my arthritis from my medical records.  |
| I understand that I am participating in a study visit, which may take up to one hour. |
| I understand that if any medical problems requiring follow-up are found, my GP or usual healthcare provider will be informed.  |
| If I decide after the visit to withdraw from the study, I have the right to withdraw my collected information as long as I inform the study researchers within 2 weeks. |
| I understand if I decide to withdraw from the study more than 2 weeks after the visit, the information collected may continue to be processed as part of the study. |
| I understand I do not need to give a reason to withdraw from the study. |
| I understand that after the study ends, all physical data will be stored securely at the Department of Medicine at the University of Auckland or transferred to a secure archiving site, and all electronic data will be stored on a password protected data server at the University of Auckland accessible only to the study researchers. After 10 years, all paper forms will be shredded and all electronic data will be erased.  |
| 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 know who to contact if I have any questions about the study in general. |
| I would like to receive a copy of the study results after the completion of the study. | Yes □ No □ |

**Declaration by participant:**

I hereby consent to take part in this study.

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| Participant’s name: |
| Signature: | Date: |
| Participant mailing address (for results of the study to be sent): |

**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.

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| Researcher’s name: |
| Signature: | Date: |