

# Participant Information Sheet



**Date Information Sheet Produced:** 17<sup>th</sup> June 2016

**Project Title:** Foot and ankle characteristics in people with systemic lupus erythematosus

## **An Invitation**

We would like to extend a warm invitation to you to participate in a research project being undertaken at AUT University. This project will gather important information on the various ways lupus may affect the foot and ankle.

## **What is the purpose of this research?**

Systemic lupus erythematosus (lupus) is a major cause of pain and disability in Aotearoa, New Zealand. There has been very little research on the ways lupus may affect the feet. Therefore this research aims to gather information on foot problems in people with lupus. The findings from this study will assist future research to identify these effects earlier and apply well-targeted treatment plans.

## **How was I identified and why am I being invited to participate in this research?**

Your rheumatologist may have previously contacted you about the study. This project invites people who have been diagnosed with systemic lupus. You are welcome to participate if you are over 20 years of age. However, if you have a medical history of foot or ankle surgery, other types of inflammatory arthritis or other types of lupus without systemic involvement we will be unable to include you in this study regrettably. Your involvement in this project is voluntary and you are welcome to withdraw your participation at any time without reason. If you have a family member who would also be interested in participating as a volunteer who does not have lupus then please let the researcher know.

## **What will happen in this research?**

We will ask you to attend a visit at the AUT North Shore campus. At this visit you will be asked to complete questionnaires relating to your feet. You will then take part in standard clinical assessments that will help us gather information about your feet and your walking. We request that you do not consume caffeine, alcohol or smoke cigarettes at least an hour before your appointment and please note that some of these tests will require you to lie down flat for a period of 20 minutes. We anticipate the process will take approximately 90 minutes.

## **What are the discomforts and risks?**

There are minimal risks and discomforts with these assessments.

## **How will these discomforts and risks be alleviated?**

Please let us know if you experience discomfort at any time and we will do everything we can to make you feel as comfortable as possible. You will also be allowed to rest at any point during the walking assessment.

## **What are the benefits?**

The aim of this study is to build a foundation of knowledge on lupus and the feet. It will also identify the level of foot pain and disability in people with lupus compared to people without lupus. By doing so, health care professionals will be able to understand the extent of foot problems in people with lupus. Participants will also receive a summary of findings once the research is completed.

**What compensation is available for injury or negligence?**

In the unlikely event of a physical injury as a result of your participation in this study, rehabilitation and compensation for injury by accident may be available from the Accident Compensation Corporation, providing the incident details satisfy the requirements of the law and the Corporation's regulations.

**How will my privacy be protected?**

Your name, birthdate and any personal information that could identify you as an individual will not be used in this study or published in any medium. All the information that is provided by you will be treated as confidential and strict access will only be available to the researchers and yourself upon request.

**What are the costs of participating in this research?**

There will be no financial cost to you if you decide to participate in this research. You will be reimbursed for your travel to and from AUT with petrol vouchers.

**What opportunity do I have to consider this invitation?**

You have two weeks to decide whether or not you would like to accept this invitation. I would like to arrange an appointment time with you at least one week beforehand so that I can secure the equipment needed for this study. Please make sure you thoroughly read this Information Sheet and have any concerns answered before you participate.

**How do I agree to participate in this research?**

If you would like to participate in this study please contact me (Sarah Stewart) via the details given below. I will then give you a Consent Form (or send one if requested) to fill out and sign.

**Will I receive feedback on the results of this research?**

If you are interested to see the outcomes of this research please indicate so on the applicable section of the Consent Form. The results will be sent to you in the form of a written summary and any papers that may be published as a result of this study can be accessed upon request.

**What do I do if I have concerns about this research?**

Any concerns regarding the nature of this project should be notified in the first instance to the Project Supervisor, Professor Keith Rome (contact details below). Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEK, Kate O'Connor, [ethics@aut.ac.nz](mailto:ethics@aut.ac.nz) 921 9999 ext 6038.

**Whom do I contact for further information about this research?**

Please contact the researcher by phone or email:

**Sarah Stewart**

**Phone: 0800 210 006**

**Email: [sarah.stewart@aut.ac.nz](mailto:sarah.stewart@aut.ac.nz)**

**Project Supervisor Contact Details:** Professor Keith Rome; Phone: 09 921 9999 ext. 7688; Email: [krome@aut.ac.nz](mailto:krome@aut.ac.nz)