

## **Participant Information Sheet**

### **Feasibility Study: Person living with diabetes**

**Study Title:** Investigating plantar pressure measurements and their potential role in a local diabetes foot screening pathway.

#### **Invitation**

Thank you for taking time to read this form. We would like to invite you to take part in a research study which involves you having your foot pressures measured by walking on a platform with sensors. Choosing not to take part will not disadvantage you in any way. Before making any decision it's important you understand why the research is being done and what your role will be. Please read the following information and feel free to contact us if anything is unclear or you require further information.

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

The study aims to gather information on foot pressures in people with diabetes. People with diabetes have a higher risk of developing foot problems and we want to work out if people with higher foot pressures are more likely to develop foot problems. We want to see if there is a way of identifying people with foot problems at an earlier stage.

#### **Why have I been chosen to participate?**

We are looking for people with diabetes in Highland region. You are being invited to take part because you have been identified as someone living with diabetes.

#### **Do I have to take part?**

No. It is up to you whether to take part. If you do decide to take part, you will be given this information sheet to keep and asked to sign a consent form. You are free to withdraw at any time and without giving a reason and a decision to withdraw or not to take part, will not affect the standard of care you receive.

#### **What will happen to me if I take part?**

This study involves using a device to measure foot pressures. The measurements will be taken in the clinic area before or after your diabetes or eye screening appointment. This is expected to add around 30 minutes to your clinic visit. First, your weight and height will be measured if not recorded recently.

You will stand on a flat platform. You will then walk across the platform 3 times.

#### **What are the possible disadvantages and risks in taking part?**

There are no foreseeable risks associated with the study. If you have any concerns about managing your diabetes during the study you will be able to speak to a diabetes specialist.

**What are the possible benefits of taking part?**

You have the opportunity to help us understand the use of foot pressures in screening for foot problems in people with diabetes.

**What if something goes wrong?**

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concern about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanism is available to you.

**Will my taking part in this study be kept confidential?**

All the information we collect will be kept confidential and will be stored securely. Only the research staff will have access to your personal or identifying information. All information resulting from this research which identifies you will be kept strictly confidential, but may be inspected by regulatory authorities. Your GP will not be notified of your participation.

**What will happen to my data in the future?**

The information collected from this study will be used to inform a larger study. The results of this project may be presented in academic meetings, or published in scientific journals; there will be no information in the publication which will identify you.

**Who is organising the funding of the project?**

This project is being organised by members of the University of the Highlands and Islands, Division of Health Research and NHS Highland, under the direction of Professor Sandra MacRury.

**Who Reviewed this Study?**

This study has been reviewed and received ethical approval from the University of the Highlands and Islands and NHS research ethics committees.

**Contact for further information?**

Professor Sandra MacRury  
Chair of Clinical Diabetes, Division of Health Research Tel 01463 279583

**Independent Contact for Information**

Dr David Macfarlane  
Consultant Diabetologist, Raigmore Hospital, Inverness Tel 01463 704000