**Nottingham**

**Biomedical Research Centre**

**Participant Information Sheet**

**(Final version 2.0: 11 May 2018)**

**Title of Study: Investigating Musculoskeletal Health and Wellbeing**

**IRAS Project ID:** 227758

**Name of Researcher:** David Walsh

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Ask us if there is anything that is not clear

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

Many conditions (such as arthritis and even normal ageing) affect the musculoskeletal system (muscles, bones and joints), can cause unpleasant symptoms such as pain and fatigue, and can prevent people from doing the things they want or need to do. In many cases available treatments might help, but are not cures and might not always relieve the most severe symptoms. More research is needed to find new and improved treatments.

One reason why current treatments can be less helpful than we’d like is if only some rather than all people benefit from them, or if they only work for some rather than all musculoskeletal symptoms. We aim to find ways of getting the right treatments to the right people at the right time. To do our research we need to be able to find people with particular characteristics or symptoms. We wish to use the information that you provide to characterise how different musculoskeletal problems develop or progress. If you agree, we may contact you about future research that might lead to better treatments for people like you, now or in the future. We also hope that by joining this study the information that you provide will enable us to use simple questionnaires to help identify people or problems that will benefit from existing or new treatments.

**Why have i been invited?**

We are looking for volunteers aged 18 or over. Most people will experience a musculoskeletal problem at some time in their life and our research can benefit from a wide range of volunteers. At this stage in our research, our questionnaires are only available in English.

**DO I HAVE TO TAKE PART?**

It is up to you to decide whether or not to take part. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

**What will HAPPEN TO ME if I take part?**

We are asking you to fill in a questionnaire about your musculoskeletal health and how you feel. We expect you will need **less than 15 minutes to complete** the questionnaire. It is fine to take a break between questions but we do ask you to complete them all within the same day. We are also asking whether you would allow us to contact you again to invite you to fill in an updated questionnaire, each year for the next 5 years, or to let you know about our other research. If you agree, we may also use for our research information in your health record (such as X-ray reports) where it might be relevant to your musculoskeletal health and wellbeing. Your data may be used to facilitate nested study design. In this study design, a cohort of people with the condition of interest are recruited, and consented to approach for future studies. If you serve as a control your data may be used in a trial context without notification. Your questionnaire can be useful to us even if you choose not to do the other things that we ask.

**Can I change my mind?**

Yes, you are free to have your contact details removed from our database and unlinked from the research data at any time and you do not have to give a reason. However, once we have used your questionnaire in our research, we would not be able to remove your answers from our results.

**EXPENSES AND PAYMENTS**

Everyone who completes the study questionnaire can, if they wish and give us their contact details, be entered into a prize draw. The winner will be notified by email or post. They can choose either to receive £100 of shopping vouchers or we will make a £100 donation on their behalf to their chosen charity.

**What are the POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?**

Some people might find answering questions about their health and wellbeing distressing. If you have particular concerns about your health we advise you to discuss them with your doctor.

**What are the POSSIBLE BENEFITS OF TAKING PART?**

We do not expect you to benefit directly from this study, but with your help we hope to gain a better understanding which will help improve treatments in the future.

**What do I need to do now?**

If you agree to participate in this research study, please complete the questionnaire and consent form and send them to us using the prepaid envelope provided. Please keep this information sheet for your records.

# **What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting the NUHT PALS Department on 0800 183 0204.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

# **WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?**

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept strictly confidential, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data).

All data including your personal data (address, telephone number) will be kept securely for 7 years after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). Questionnaire responses will be used to identify groups that are suitable for particular trials and this data will remain linked to their personal data so that these participants can then be contacted. Access to the linked data set will be restricted to the Data Custodian and members of the research team authorised by the Data Custodian. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

In accordance with the University of Nottingham’s, the Government’s and our funders’ policies we may share our research data with other Universities and researchers, including those in other countries. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

# **WHAT WILL HAPPEN IF I DON’T WANT TO CARRY ON WITH THE STUDY?**

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. You will be contacted annually to see if you are still happy for your data to be still kept for the purposes explained. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis, but it will not be used for the other purposes.

HOW WILL MY INFORMATION BE USED?

If you agree, we may use your contact details to send you annual follow-up questionnaires and may invite you to help us with other research into musculoskeletal health and wellbeing. The information you provide may also be used to see if there are groups of characteristics that might enable us to identify people who could benefit from particular treatments and to select appropriate groups for studies. The information collected about you may be used to facilitate nested studies (studies which recruit participants from a population whose characteristics are known because its members are already the participants of an existing larger study). If it is used as part of a control group (a group of individuals who do not receive the treatment whose information allows comparison with those receiving the treatment in order to determine its effectiveness), the data may be used in a trial context without notification. Your data may also be used for audit/evaluation and to help us to design future studies.

**WHO IS ORGANISING AND FUNDING THE RESEARCH?**

This research is being organised by the University of Nottingham and is being funded by the NIHR and Arthritis Research UK.

**Who has reviewed the study?**

This study has been reviewed and given favourable opinion by [London Central Research Ethics Committee]

**WHO CAN I CONTACT IF I HAVE ANY QUESTIONS ABOUT THIS STUDY?**

If you have any further questions about this study please contact the Research Coordinator and Study Contact: **Telephone** 0115 8231754**; Email** [**msk-recruitment@nottingham.ac.uk**](mailto:msk-recruitment@nottingham.ac.uk)**; Address** Academic Rheumatology, University of Nottingham, Clinical Sciences Building, City Hospital Nottingham, NG5 1PB.

Results from this study will be available at [www.nottinghambrc.nihr.ac.uk](http://www.nottinghambrc.nihr.ac.uk/) and <https://twitter.com/MskWellbeing>. Paper copies can be obtained from the Study Contact.

**Thank you for taking the time to read this invitation**