Participant Information Sheet

Health and Social Science Research

Adult providing own consent Liverpool Hospital

Title	Documenting long-term outcomes in patients with musculoskeletal disease using quantitative data from patient and physician questionnaires
Short Title	Quantitative patient and physician questionnaire data
Protocol Number	LNR/13/LPOOL/370; SSA REF: LNRSSA/13/LPOOL/371; Local Project No: 13/229LNR
Coordinating Principal Investigator/ Principal Investigator	Kathryn Gibson
Location	Liverpool Hospital

Part 1 What does my participation involve?

1 Introduction

You are invited to participate in a research study into how well patient questionnaires are able to detect symptoms in arthritis patients, both to assist in clinical care and to monitor patient outcomes. The study is being conducted by A/Prof Gibson and colleagues in the Rheumatology clinics at Liverpool Hospital.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read this Participant information sheet carefully and discuss it with others if you wish. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research. Ask questions about anything that you don't understand or want to know more about.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

2 What is the purpose of this research?

The purpose of this research is to compare the clinical severity of a variety of different kinds of arthritis. Information collected from patients by questionnaires is known to be useful for monitoring the severity of arthritis and response to treatment and helps us to understand the outcomes of these illnesses over time. This research will also study how clinicians decide if your symptoms are due to inflammation, joint damage or other factors. This assessment is known to influence treatment intensification in clinical trials. It is important to understand what factors other than inflammation may influence physician assessment as this may change treatment decisions.

3 What does participation in this research involve?

If you decide you want to take part in the research project, you will be asked to sign a consent section on the "Multidimensional Health Assessment Questionnaire (MDHAQ)" form. If you require an interpreter to assist you to understand the consent that will be provided for you. By signing the consent you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to be involved in the research as described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet to keep.

You will also be asked to complete a range of questionnaires that may change from time to time. These questionnaires will be on paper or delivered to you by an email link to an electronic version of the same forms. You are asked to complete them the day before your scheduled appointment or at the appointment if you have not completed them before attending. In general, completion of the forms will take 10-20 minutes. If you do not understand any questions or think they need to be explained please ask the clinician looking after you. Please do not be concerned about giving incorrect answers. Whatever you think is correct is the right answer for you.

Your information will only be seen by the clinicians looking after you in the clinic and researchers as explained in the consent. The paper information will be stored securely in the Rheumatology department at Liverpool Hospital and will be entered into a secure REDCap database hosted at the University of New South Wales.

4 Other relevant information about the research project

Participation in this study will not cost you anything. There is no payment for participation in the study. Completion of the questionnaires will take you about 10 minutes. Any identifiable information that is collected about you in connection with this study will remain confidential. Confidential information about you will be disclosed only with your permission, or as required by law.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you choose not to participate, your management by the Rheumatology department will not be affected and there will be no adverse impact on your care.

6 What are the possible benefits of taking part?

This study aims to further medical knowledge and improve future management of people with arthritis, however it may not directly benefit you. Sometimes answering a questionnaire is easier than raising specific problems with your doctor. If you do wish to discuss any of your answers specifically with your doctor, please feel free to do so during your consultation.

7 What are the possible risks and disadvantages of taking part?

If any of the questions in the questionnaires cause you distress, or if you would like to discuss any of the questions further, please raise this will your treating doctor, the clinic nurse, or your General Practitioner. If you do not wish to answer some of the questions you do not have to.

8 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team or your treating doctor. If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

9 Could this research project be stopped unexpectedly?

Limitations including but not limited to lack of funding may stop this research project unexpectedly.

10 What happens when the research project ends?

The aim of this research is to build up a long term database of patient reported information that will help us to understand the outcomes of a range of participants with arthritis in the real world. This information will continue to be collected for as long as ethical approval continues. It will be analysed and prepared into reports. The de-identified results may also be presented at Australian and International meetings.

In any publication, information will be provided in such a way that you cannot be identified. Should you wish to review the published report or material you have disclosed, you may do so by contacting the researcher.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

By signing the consent form you consent to the research team collecting and using personal information that you provide for the research project and that can be obtained from your health records held at Liverpool Hospital that is relevant for the purpose of this research. Any information obtained in connection with this research project that can identify you will remain confidential. Only information relevant to your clinical management will be stored with your medical record file. The questionnaire data will be stored in a locked filing cabinet in a secure office within Liverpool Hospital Rheumatology Department. Only researchers involved in the project will have access to the data and it will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Electronic data will be kept on the secure REDCap database hosted at the University of New South Wales. Access to the database will be restricted to IT support staff and personnel working with the Liverpool Rheumatology Department. Database users will only be granted access to data that they have ethics approval to access. After completion of the study the data will be stored securely for 5 years and then destroyed in a confidential manner. It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your written permission.

12 Compensation

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

13 Who is organising and funding the research?

This research project is being conducted by Clinical A/Prof Kathryn Gibson.

14 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of South Western Sydney Local Health District. This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

15 Further information and who to contact If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the A/Prof Gibson on 8738 4088 or by email at: SWSLHD-LiverpoolRheumatology@health.nsw.gov.au

The conduct of this study at **Liverpool Hospital** has been authorised by the South Western Sydney Local Health District, any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer on (02) 8738 8304, email: SWSLHD-Ethics@health.nsw.gov.au and quote project number : 13/229LNR

Thank you for taking the time to consider this study.