# OPAL PHASE 1 - PARTICIPANT INFORMATION SHEET

We would like to invite you to take part in a research study aimed at helping people return to work following their hip or knee replacement surgery.

As part of this study we are interested in collecting information from you and hearing your views and experiences about your recovery and return to work following your joint replacement.

Before you decide whether to take part in the research study, it is important for you to understand why this is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please feel free to ask us if there is anything you are not sure about.

**Why are we doing this research study?**
Hip and knee arthritis causes pain that limits physical function and can affect ability to work. Hip and knee replacements are proven to relieve pain and improve function, and can help many patients of working age to continue working or get back to work.

However, currently there is much we do not know about patients returning to usual activities and work following hip and knee replacement. We therefore need to better understand what is currently being done and how we might improve current care. Once we understand the issues patients have when returning to work after hip and knee replacement we will develop advice to help people return work. This advice will be in the form of a manual that will provide support to help patients return to usual activities including work following their operation.

**How long will the study last?**
This research has two separate parts and will take 27 months overall - however you will not be involved for the whole study.

The first part will collect information about work roles and return to work from a variety of sources including patients using questionnaires and interviews and will run during the first 12 months of the study. In the second part we will use this information to develop the manual to help patients return to usual activities including work. We are currently inviting patients to help us with the first part of the study (questionnaires and interviews) but may later contact you again to request your help with the second part of the study.

**Why have I been invited?**
You have been invited because you are about to receive or have recently had a hip or knee replacement at one of the hospitals participating in this research. You have also been in work at some point during the last 6 months.

**Why are we performing questionnaires and interviews?**
The purpose of these is to gather information about your general health, employment and work. Information is also requested about when and how you return to work after your operation or, for those patients that do not return to work, why this was. By collecting this information we will be able to understand what issues prevent people returning to work after their operation. All patients who agree to take part will complete questionnaires but only some will be asked to undertake an interview.

**What will happen to me if I take part in the questionnaires and interviews?**
If you decide to take part in the questionnaire part of the study, you will be asked to complete the initial questionnaire while in hospital and then follow up questionnaires at 8 & 16 weeks after your operation. Some patients will also receive a follow up questionnaire at 24 weeks. These questionnaires can be completed either at the hospital if you have a hospital visit or they can be sent to you by post. You will be contacted about completing these questionnaires by a member of the research team. If necessary they can also be completed over the telephone. Questionnaires will take approximately 30-40 minutes of your time to complete at each time point.

If you also agree to take part in the interview part of the study, we will send your contact details to researchers from the University of Nottingham. They will contact you to arrange an interview to discuss in greater detail the work you do, and what advice and support you received to help you return to work and your usual activities following your surgery. The interview will last approximately 30 minutes and can be completed face-to-face or via telephone, at a time that suits you. The face-to-face interview can be conducted either at your local hospital or another agreed place. The interview will be audio recorded, with your consent, and transcribed but personally identifiable information, such as your name, will be removed.

**Will you be interviewing anyone else?**
Yes, in order to gain a complete picture about how and when patients return to work, we need to interview other people involved in their care. We therefore plan to interview a variety of different people including surgeons, General Practitioners, physiotherapists, occupational therapists, employers and workplace representatives. Some of the healthcare professionals interviewed may be those involved in your care. However, we will not be interviewing your employer or workplace representative.

**Do I have to take part and allow you to contact my workplace representative?**
It is up to you to decide whether or not you wish to take part in the study and in which parts of the study you would like to participate. In summary there are 2 key elements that we are asking patients to help with:

- Questionnaire completion
- Participating in an interviews

You have some time to think about taking part in this research study and do not need to decide straight away. A member of the research team will contact you to ask you which parts of the study, if any, you might like to be involved in. They will also be able to answer any further questions you may have. If you do want to take part you will be asked to sign a consent form. Different options are available on the consent form reflecting the different elements of the study that we need help with (listed above).

**What are the possible disadvantages and risks of participating?**
There are no particular risks associated with this study. We appreciate that taking part will involve your time.

**What are the possible benefits of taking part?**
There may be no direct benefit to you. However, the information we collect from the study will help us understand patients' experiences of the support and advice they receive and will identify improvements that might be made in the future. Participants will be helping to shape and improve advice for those patients hoping to return to work after hip or knee replacement in the future.

**Will it cost me anything to take part?**
It will not cost you anything to take part in the study. We will provide paid return mail envelopes for the questionnaires if they are being completed by post. The interview will

take place at your home, at your local hospital or by telephone, whichever is easiest for you. Any travel expenses will be reimbursed.

**Will the information I provide be kept confidential?**

Yes, we will follow established ethical and legal practices, and all information collected about you during the course of the study will be kept strictly confidential. Some parts of the data collected for the study will be looked at by authorised persons from the research team 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.

Any information we collect about you will be stored in a secure location and electronically on a password protected database. We will store personal contact information, such as your name, address and telephone number, so we are able to contact you about the study; as well as your NHS number. This information will be held in a separate file from the questionnaires and interview recordings/transcripts. Some of the questionnaires may ask for your age, gender, date of surgery, and the first part of your postcode as we need to collect this information for the study. Any other information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used to help protect your identity.

Your personal data (address, telephone number) will be retained after the end of the study for up to three years, in the event that we need to contact you about the findings of the study (unless you advise us that you do not wish to be contacted). Only members of the research team (University of York & University of Nottingham, the Sponsor (South Tees Hospitals NHS Foundation Trust) and the NHS Trust) will have access to your personal data. We will ask for your consent to link the data collected from the study to routinely collected health data stored in national databases (via your NHS number), and to share this information anonymously with other researchers. Your personal details will not be provided to anyone else, or used for any other purpose.

Your personal data will be disposed of securely after it is no longer necessary to contact you. All other research data will be stored securely for seven years, and after this time will also be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality. However, if you make a disclosure to a member of the research staff, which makes them seriously concerned about you or someone else's safety or well-being, then the researcher is obliged to break confidentiality in accordance with the Human Rights Act 1998.

**What if there is a problem?**

If you have any concerns or questions about any aspect of this study, you should ask to speak to the researchers (their contact details are at the bottom of this sheet), who will do their best to answer your questions. If you would like to speak to someone outside the research team, you can do this by contacting the Sponsor: XXXXXXX, Tel: XXXXXXX or Email: XXXXXXX@XXXXXXX

If you remain unhappy and wish to complain formally, you can do this through the National Health Service complaints mechanism by contacting the Patient Advice and Liaison Services (PALS) officer at your hospital on free phone XXXXXXX.

**What will happen if I don't want to carry on with the study?**

Your participation is voluntary and you are free to withdraw your participation (fully or partly) or permission to contact your employer or workplace representative at any time, without giving any reason. This will not affect your working and legal rights. If you

withdraw, then the information collected so far cannot be erased and this information may still be used in the project analysis.

**What will happen to the results of the research study?**
The results of the study may be presented to other researchers, at conferences and through publication in scientific journals. Results of the study may also be used to support other research in the future, and may be shared anonymously with other researchers. As requested by the funder (the HTA), we would like your permission to link the data collected during this study to the routinely collected health data stored in national databases in future, although this activity does not form part of this research project. We will ensure that it will not be possible for anyone to identify you from the published findings of the study. If you wish to know the results of the study, we will send you a summary of the findings.

**Who is organising and funding the research?**
The research is organised by South Tees Hospitals NHS Foundation Trust in Middlesbrough in collaboration with the University of Nottingham and the University of York. The research is funded through the National Institute of Health Research, Health Technology Assessment Programme.

**Who has reviewed the study?**
All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the XXXXXXX ethics committee.

**What should I do now?**
Please think about whether or not you would like to take part in the study and in which parts of the study you wish to be involved with – these are the questionnaire study and the interview. If you would like to take part please complete the consent form and either return it to one of our research nurses or send it back to us in the freepost envelope provided. A member of the research team will then contact you about the parts of the study you have agreed to help us with.

Please ask a member of the research team if there is anything that is not clear, or if you would like more information.
Principal Investigator: XXXXXXX Tel: XXXXXXX
Research Associate/ Nurse: XXXXXXX Tel: XXXXXXX

Further information and contact details: XXXXXXX

Thank you for taking the time to read this information sheet and to consider this study.