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Participant Information Leaflet and Consent Form

PURPOSE

Pressure UlceR Programme Of ReSEarch

Pain Prevalence - Prevalence of localised pressure ulcer related pain

A large-print version of this sheet is available on request.

We would like to invite you to take part in a research project. Before you decide to take part, it is important for you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and discuss it with your relatives and your ward/community nurse if you wish. Ask us if there is anything that is not clear or if you would like more information. Part 1 tells you the purpose of this project and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Part 1

What is the purpose of the study?

The purpose of this study is to see how many people who are in hospital or being treated by community nurses have pain, soreness or discomfort in one of the areas where pressure ulcers, or bed sores, commonly develop (like the lower back, buttocks, and heels). This information will be used by healthcare practitioners to improve assessment and treatment of localised skin and pressure ulcer pain.

Why have I been invited to participate?

This study is looking at people like you who are in hospital or under the care of community nursing services and who have pain in an area that may experience pressure from being in bed or a chair. Participants from many hospitals and within the community will be asked to take part.

Do I have to take part?

Taking part in this study is entirely voluntary and you are under no obligation to take part – it is up to you to decide. We will describe the study to you and go through this information sheet. If you agree to take part you will be asked to sign the consent form at the end of this leaflet to show that you have agreed to take part. You will be given a copy of this information sheet and of the consent form to keep. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. If you do not wish to take part this will not affect the care that you are currently receiving.

What if I would like to take part but I have trouble with or am unable to write?

If you would like to take part but cannot or find it difficult to write, you can have someone (a witness) complete the written part of the consent for you. This witness could be a friend, a family member, or member of your healthcare team. The witness will only act to help you carry out your wishes – you are free to change your mind at any time and your wishes will be respected.

What will happen to me if I take part?

If you agree to take part in the study, a nurse will ask you a few extra questions, assess your skin sensation, and check your skin (or pressure sore if you have one). This single assessment will take place in your own home or on the hospital ward you are on at a time convenient for you.

What are the possible disadvantages and risks of taking part?

This study is a one-off assessment which should take about an hour. We do not foresee any disadvantages or risks to you in taking part in this study. However, you are being asked to give some of your time for taking part. Your care and treatment will remain the same whether or not you decide to take part.

What are the possible benefits of taking part?

There will be no direct benefit to you as a result of participating in this study. We hope that the information from this study will help to improve awareness and treatment of pressure ulcer related pain in the future.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak with your healthcare practitioner or other healthcare professional who will do their best to answer your

questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. In the unlikely event that you think you have been harmed by taking part in this study, there are no additional compensation arrangements. Details about complaints procedures can be obtained from your healthcare practitioner.

Will my taking part be kept confidential?

Yes. All information which would be collected about you during the course of the study will be kept strictly confidential. We will follow ethical and legal practice and all information about you will be handled in confidence.

This completes Part 1 of the Information Sheet. If the Information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

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

Taking part in this study is entirely voluntary and you are free to change your mind at any point during or following completion of the study without giving a reason. A decision to withdraw at any time will not affect the standard of care you receive, nor will it affect your relationships with your doctors and nurses in any way.

Will my taking part in this study be kept confidential?

If you decide to participate in the study, the information collected about you during the course of the study will be anonymised and kept strictly confidential. This information will handled, processed, stored, and destructed in accordance to the Data Protection Act 1998. The study team have a duty of confidentiality to you and will do their very best to meet this duty. Any information that is collected about you, including any additional information obtained from your medical records, will have your name and address removed from it. All information obtained is strictly confidential and will be kept in locked cupboards and will only be accessible to members of the research team. No names or details that would identify specific people will be included in the outputs from this study. Outputs may include reports, presentations, and papers (published in a medical journal), and further healthcare and/or medical research, but these will not be traceable to specific individuals.

Who has organised and sponsored the research?

The study is being organised and coordinated by the Clinical Trials Research Unit (CTRU) at the University of Leeds, who is sponsoring the study. This study is a part of a larger pressure ulcer research programme funded by the National Institute of Health Research that aims to reduce the impact of pressure ulcers on patients.

Who has reviewed the study?

The study has been peer reviewed by the National Institute of Health Research before approval for the funding was given. In addition, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing, and dignity. This study has been reviewed by the Leeds Central Research Ethics Committee (reference 09/H1313/14).

Further information and contact details

If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations working together on clinical research in the UK) have published a booklet entitled 'Understanding Clinical Trials'. Contact UKCRC: Tel: 0207 670 5452; website www.ukcrc.org

Your contact telephone numbers:

(*to include local PI*) ……..

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Patient Study Number:	DOB:
Principal Investigator:	Version: 3.0

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PATIENT CONSENT FORM

Where witnessed consent is required please use the Witnessed Consent Form

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	Patient initial after each question
1. I confirm that I have read and understand the information sheet dated 18/01/2010 (version 3.0) for the above study. I have had the opportunity to ask questions and have had these answered satisfactorily.	.....
2. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected.	.....
3. I understand that relevant sections of my healthcare records and data collected during the study may be looked at by individuals from the NHS Trust Teams and the Sponsor, where it is relevant to my study participation. I give permission for these individuals to have access to my records.	.....
4. I agree to take part in the study.	.....

_____ _____ _____

Name of Patient Date Signature

I have given written information and a verbal explanation to the person named above who has freely given their consent to participate.

_____ _____ _____

Name of Person taking consent Date Signature

(1 copy for patient; 1 for patient records; original stored in Investigator Site File)