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PURPOSE

Pressure **U**lc**R** **P**rogramme **O**f Re**SE**arch

Pressure Ulcer Risk Assessment Framework (PURAF) Field Test 1

CONSULTEE INFORMATION SHEET

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

As the relative, carer, or friend of the patient I would like you to consider their participation in a research study. As he/she is unable to tell me whether they would be willing to take part themselves, I am asking you, as someone who has a close personal relationship with the patient, to consider this invitation on their behalf and respond as you think they would respond. It is important that you should consider their past or present wishes and feelings regarding research of this nature. You may have personal views on participation in this particular research project but I am asking you to advise on their views.

Before you decide whether he/she should take part we would like to explain why the research is being done and what it will involve. Please read this information carefully, and discuss it with anyone else you wish to, for example relative, friend, nurse or doctor. Ask us if anything is unclear, or if you would like more information. Part 1 tells you the purpose of this study and what taking part involves. Part 2 gives you more detailed information about the study. Thank you for reading this information sheet.

Part 1

What is the purpose of the study?

This study is part of a larger study which is trying to find a better way of identifying patients who are at risk of developing pressure ulcers (bed sores) and those who already have pressure ulcers. A group of experts and patients have worked together to work out a list of questions to ask about patients and this study is to check whether we can use this list to give reliable and consistent answers. We hope that the answers to these questions will give a good indication

of whether people are at risk of developing a pressure ulcer or not, or if they have a pressure ulcer.

Why has the patient been chosen?

This study is looking for patients' who are in hospital or under the care of community nursing services. Hospital patients and patients within the community will be asked to take part. The study includes people with different levels of walking and movement ability. This includes people who are able to move easily, as well as people who have difficulty moving or are unable to move. It will also include some people who already have a pressure ulcer.

Does the patient have to take part?

No, they do not have to take part. Taking part in this study is entirely voluntary and there is no obligation to take part – it is up to you to decide whether or not you feel it is appropriate for them to take part. If you are interested we will describe the study to you and go through this Information Sheet. If you agree for the patient to take part you will be asked to sign a Consultee Declaration Form to show that you have been consulted about the patient participating in the study and have agreed it is appropriate for them to take part. You will be given a copy of this Information Sheet and of the signed Consultee Declaration Form to keep. If you do not feel it is appropriate for the patient to take part this will not affect the care that they are currently receiving.

If you agree for the patient to take part you are free to change your mind and withdraw them from the study at any time, without giving a reason. This would not affect the standard of care they receive.

If you do not feel able to advise on the patient's views you may suggest someone else who has a close relationship with them or ask me to nominate a consultee, such as a doctor or nurse not involved in this study who knows the patient. If a nominated consultee is approached they will probably discuss the patient's wishes with you before they give advice.

What will happen to the patient if I agree they can take part?

If you agree to the patient taking part in the study, two nurses will undertake an assessment that will involve referring to relevant sections of the patient's nursing and medical records

and asking the patient some questions (if applicable) relating to their health. Both nurses will also look at the patient's skin in the areas which are exposed to pressure. This includes having a quick check of your elbows, heels, and bottom, which are the areas that are most at risk of getting a pressure ulcer. The nurses will also look at their pressure ulcer if they have one. With your agreement, one nurse will come and repeat the assessment a few days later at a time convenient to the patient. The questions and skin check will take about 20 minutes and will take place in the patient's own home, or on the hospital ward they are on, at a time convenient for them.

What are the possible disadvantages and risks of taking part?

We do not foresee any disadvantages or risks to the patient in taking part in this study. However, they are being asked to give some of their time for taking part. The patient's care and treatment will remain the same whether or not they take part in the study.

What are the possible benefits of taking part?

There will be no direct benefit to the patient as a result of participating in this study. However, we hope that the information from this study will help to improve the assessment, prevention and treatment of pressure ulcers 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 the patient's healthcare practitioner (e.g. Nurse or Doctor) 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 the patient has been harmed by taking part in this study, there are no additional compensation arrangements. Details about complaints procedures can be obtained from the patient's healthcare practitioner, or PALs (Patient Advice and Liaison Services).

Will taking part be kept confidential?

Yes. All information which would be collected about the patient during the course of the study will be kept strictly confidential. We will follow ethical and legal practice and all information about the patient will be handled in confidence. No names or details that would

identify specific people from this study will be included in any reports, presentations or papers (published in a medical journal), or further healthcare and/or medical research.

Involvement of the patient's General Practitioner (GP) / Other Healthcare Practitioner

The patient's GP will be informed that they are participating in this study. If the patient is under the care of a Hospital consultant (inpatients only), they will also be informed of the patient's participation.

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

Part 2

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

Taking part in this study is entirely voluntary and you are free to change your mind about the patient participating in the study 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 the patient receives, nor will it affect their relationship with the medical and nursing team who are looking after them. Should you choose to withdraw the patient, then their existing data (until withdrawal) will remain on file and will be included in the final study analysis unless you specifically withdraw consent for this.

Will taking part in this study be kept confidential?

If you decide the patient can participate in the study, the clinical information collected about them during the course of the study will be anonymised and kept strictly confidential. We will record their date of birth and initials on all study forms. If you agree to the second assessment the study nurse will record their NHS ID, hospital number (hospital patients only) and address and telephone number (community patients only). This will be held only by the study nurse who will destroy this information immediately following their second assessment. A copy of the Consultee Declaration Form you sign, which will include your name and the patient's name, will be sent to the Clinical Trials Research Unit. They do not put your names on computer. They simply check that the Consultee Declaration Form has been signed and dated properly and will securely file the form.

All information will be handled, processed, stored, and destroyed in accordance with the Data Protection Act 1998. The study team have a duty of confidentiality to the patient and will do their very best to meet this duty. 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 from this study will be included in any reports, presentations or papers (published in a medical journal), or further healthcare and/or medical research.

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, which 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 in order to protect your safety, rights, wellbeing, and dignity. This study has been reviewed by the Leeds West Research Ethics Committee (reference 12/YH/022).

What will happen to the results of the research study?

When the study is complete the results will be published in a medical journal, but no individual participants will be identified in any report or publication. If you would like to obtain a copy of the published results, please ask your local contact person (see contact details below). We hope that the information from this study will help to improve the assessment, prevention and treatment of pressure ulcers in the future.

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. If you want any further information about the study, now or in the future, please contact (insert name here) below.

Your contact telephone numbers: (*to include local collaborator*)…….

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