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PURPOSE

Field test 1 & sub-study participant information leaflet and consent form

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 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 development of pressure ulcers, also called a bed sore or pressure sore, can have a major impact on patients' quality of life and well-being as well as severely compromise all areas of functioning. However, there is currently no formal way of assessing quality of life from the patients' perspective in healthcare and in research, as there is no quality of life questionnaire for use with patients with pressure ulcers.

The Pressure Ulcer Quality of Life (PU-QOL) project will develop a questionnaire that will assess important quality of life issues in patients with pressure ulcers that will be suitable for use in NHS clinical practice and in research. Specifically, the project questionnaire will provide us with important information about the experienced suffering of patients with pressures and the impact pressure ulcer treatments have on patients' quality of life. This information will be obtained in order to improve patient healthcare and patient quality of life.

This study is the third phase of the development of the project questionnaire and involves patients like you, either completing the project questionnaire on your own or with assistance.

This study is undertaken so that we can determine whether the project questionnaire is a useful questionnaire for assessing quality of life in people with pressure ulcers.

Why have I been invited?

You have been chosen to take part because we wish to develop this questionnaire from the perspective of people who have a pressure ulcer. This will ensure that the questionnaire covers issues that are important to patients who are affected by pressure ulcers ranging from a small red area to a more severe ulcer. Participants from many hospitals and from 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 in this study, 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 for you 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, career, or member of your healthcare team not directly involved in the research. 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, you will be asked to complete a questionnaire booklet either on your own in your own time or with assistance. Completing this booklet will take approximately 40 minutes. It would involve choosing an answer to a set of questions on a response scale. An example of a question that you might be asked is:

> In the past week, for how many days did your pressure ulcer cause you pain or ache? (*please tick one box*)
>
> None at all ☐ between 1-3 days ☐ between 4-5 days ☐ between 6-7 days ☐

When you have completed the questionnaire booklet, you will be expected to either hand it back to your district or tissue viability nurse, or send it back to the Clinical Trials Research Unit in the stamped, self-addressed envelope that was provided to you with this leaflet.

We will also ask you to complete the same questionnaire booklet 2-7 days after the first completion; however, you can opt out of this second participation if you wish. You will be asked to indicate on the consent form at the end of this information leaflet whether you would be happy to complete a second questionnaire booklet. Your anonymised, completed questionnaire booklets will be used only by researchers involved in the project and will be stored in a locked cabinet. In some instances, we may need to access your health care records to obtain additional information about your pressure ulcer and the treatments that you have received.

Expenses and payments

We anticipate that there will be no extra expenses for you as a result of taking part in this study, as completion of the questionnaires will take place in your own home or on the hospital ward where you are admitted at a time convenient for you.

What are the possible disadvantages and risks of taking part?

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 completing the questionnaires. 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 questionnaire that we are developing will help people with pressure ulcers in the future.

Will my taking part in this study 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. In the event that any evidence of poor practice, neglect or abuse is identified during the course of the interview, the researcher might need to disclose details to a third party outside of the interview. This would not be done without discussing it with you first.

This completes part 1.

If the information in Part 1 has interested you and you are considering participation, please 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 up to, during or following completion of your questionnaires. You will not be able to be identified in the study results but if you wish to withdraw any questionnaire data collected prior to publication of the results then arrangements can be made for your questionnaire to be destroyed and your responses excluded from the study.

Will my taking part in this study be kept confidential?

The procedures for handling, processing, storage and destruction will be according to the Data Protection Act 1998.

Claudia Gorecki and the project team have a duty of confidentiality to you as a research participant and will do their very best to meet this duty. Any information that is collected about you, including any additional information obtained from your health care records, will have your name and address removed so that you cannot be recognised from it. All information obtained is strictly confidential and will be kept in locked cupboards and will only be accessible by members of the research team. No names or details that would identify specific people will be included in the outputs from this study. Outputs, including quotations from interviews, may be used in reports, presentations and papers, and for healthcare and/or medical research, but these will not be traceable to specific individuals. All published and unpublished reports will disguise the identity of people.

Involvement of the General Practitioner/Family doctor (GP)

Your GP will not be notified of your participation in this study.

What will happen to the results of the research study?

Participants will not be identified in any report or publication. The study results will be based on the development of the project questionnaire. Information from this study will be included in a final report for the whole project and published in a scientific journal.

Who is organising and sponsoring the research?

This study is being undertaken as part of a PhD qualification sponsored and supervised by the University of Leeds. This study is also phase 3 of the project that is funded by the National Institute of Health Research as part of a larger PU programme aimed to reduce the impact of PUs on patients and develop methods to capture outcomes important to patients such as quality of life.

Who has reviewed the study?

This study has been peer reviewed by the National Institute of Health Research before approval for 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 and given approval by the North West Research Ethics Committee.

What do I do now?

Once you have read the information and if you would like to take part in the study, please let your district nurse or tissue viability nurse who provided you with this information leaflet know. They will ask you to complete the consent form at the end of this leaflet and either provide you with the questionnaire booklet to complete on your own or assist you in completing the questionnaire booklet. Completed booklets will be sent back to the researcher, Claudia Gorecki.

Further information and contact details

Thank you for taking the time to read this leaflet and for considering this study. If you would like to discuss the study further or have any questions about the study at any time, please contact the researcher, Claudia Gorecki on 0113 3437632 or the study supervisor, Professor Jane Nixon on 0113 3431488 or speak to your district nurse or tissue viability nurse who provided you with this information sheet.

Patient DOB: Day Month Year	Patient Study ID:

PURPOSE

PU-QOL field test 2 consent form

Name of researcher: ……

Please initial box after each question

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my nursing care being affected. ☐
3. I understand that sections of any of my health care notes or questionnaire data may be looked at by responsible individuals from the study office or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my information and questionnaire data. ☐
4. I agree to allow any information or results arising from this study to be used for healthcare and/or medical research purposes. I understand that my identity will remain anonymous. ☐
5. I consent to the storage including electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept confidential and that no personal information that could identify me will be included in the study report or other publication. ☐
6. I understand that a copy of this Consent Form will be sent to the Clinical Trials Research Unit ☐
7. I agree to take part in the above 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*

I agree to take part in completing a second questionnaire booklet in 2-7 days' time after I have completed the first questionnaire booklet. ☐

If agree to complete second questionnaire booklet, please complete contact details

Address:_____

Postcode:_____ **Telephone:** _____

(Delete this line then print on headed paper)

Patient DOB: Day Month Year	Patient Study ID:

PURPOSE

PU-QOL field test 2 witnessed consent form

Witness initial after each question on behalf of the patient

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my nursing care being affected. ☐
3. I understand that sections of any of my health care notes or questionnaire data may be looked at by responsible individuals from the study office or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my information and questionnaire data. ☐
4. I agree to allow any information or results arising from this study to be used for healthcare and/or medical research purposes. I understand that my identity will remain anonymous. ☐
5. I consent to the storage including electronic, of personal information for the purposes of this study. I understand that any information that could identify me will be kept confidential and that no personal information that could identify me will be included in the study report or other publication. ☐
6. I understand that a copy of this Consent Form will be sent to the Clinical Trials Research Unit ☐
7. I agree to take part in the above study. ☐

_____ _____

Name of Patient *Relationship of witness to Patient*

Witness statement

I have completed this consent form on behalf of the person named above who has freely given their consent to participate.

_____ _____ _____

Name of Witness *Date* *Signature*

Research person taking Consent

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*

I agree to take part in completing a second questionnaire booklet in 2-7 days' time after I have completed the first questionnaire booklet. ☐

If you agree to complete a second questionnaire booklet, please complete your contact details

Address:_____

_____

Postcode:_____ **Telephone:** _____

(When completed, original for local PI, 1 copy for CTRU, 1 copy for patient, 1 copy for patient file)