



Pressure UlceR Programme Of ReSEarch

The Development of a Pressure Ulcer Minimum Dataset (PU-MDS) and
Pressure Ulcer Risk Assessment Framework (PURAF) Study

WIDER CONSULTATION PU-MDS PARTICIPANT INFORMATION SHEET

This is an invitation to take part in the development of a Pressure Ulcer Minimum Data Set. Before you decide whether to accept, we would like to explain why the research is being done and what it will involve.

What is the purpose of this part of the study?

The purpose of this study is to agree a Pressure Ulcer Minimum Data Set (PU-MDS: a list of the data that should be collected in all settings to allow clinicians to compare patient groups and the effects of treatment).

Why have I been chosen?

We have identified that you are a person with clinical and/or academic expertise and experience in pressure ulcers.

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 after reading this information sheet and visiting the CTRU website (insert link) or contacting the study project lead (detailed below) for more information if needed. Should you decide to participate you are free to withdraw at any time, without giving a reason. If you decide to withdraw during data entry on the web-based survey platform, your questionnaire response will be incomplete. Incomplete questionnaires will be destroyed and not used in the final study analysis. If you have fully completed the questionnaire and wish to withdraw consent for your data to be used, the study data will be

destroyed, subject to provision of your study ID number which will be issued to you on completion of the questionnaire.

What does it involve?

If you agree to take part in the study, you will be invited to read a pressure ulcer risk factor systematic review summary report and complete a web-based questionnaire relating to factors for inclusion in a Pressure Ulcer Minimum Dataset. Reading the systematic review summary report will take about 30 minutes. Completing the questionnaire after that will take about 15 minutes. You will also be asked to tell us a little bit about you - your age, gender, nationality, area of expertise and current post and sector i.e. university, community or acute hospital. We do not require your name.

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 to complete the web-based questionnaire.

What are the possible benefits of taking part?

You will be contributing to the development of a Pressure Ulcer Minimum Data Set which will facilitate the interpretation and further use of pressure ulcer research data. It will also inform the development of an evidence based Pressure Ulcer Risk Assessment Framework. We hope that you will find the systematic review summary report of pressure ulcer risk factors of interest.

Will my taking part be kept confidential?

Information will be handled, processed, stored, and destroyed in accordance to the Data Protection Act 1998. If you choose to provide your contact details to allow the researcher to contact you about the results of the study, these will be stored separately to questionnaire data and held on the CTRU secure IT system which has restricted password protected access to only the CTRU research team working directly on the study. Anonymous questionnaire responses will be held on the secure web-based survey platform and will only be accessible by the web-based survey provider and the CTRU research team on a password protected restricted access database. At the end of the study, data will be securely archived at the CTRU for a minimum of 10 years and arrangements for confidential destruction will then be made.

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. The University of Leeds is acting as the study sponsor. This is a part of a programme of research on pressure ulcers funded by the NHS 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, this study has been reviewed by the University of Leeds, School of Healthcare Research Ethics Committee (SHREC).

What will happen to the results of the research study?

When the study is complete the results will be included in a final report and disseminated by publishing in scientific/ health related journals and through conference presentations.

Further Information and Contact Details

If you would like more information about THIS STUDY contact:

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What do I do now?

If after considering the above information you wish to participate please go to page two of this link to complete the questionnaire. If not, thank you for considering taking part: please close your browser window to leave the web link.