Pressure UlceR Programme Of ReSEarch

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

PU-MDS NOMINAL GROUP PARTICIPANT INFORMATION SHEET

You have been invited to take part in the study detailed above. Before you decide whether to accept, we would like to explain why the research is being done and what it will involve. Please read this information carefully, and ask us if anything is unclear, or if you would like more information.

What is the purpose of the study?

The purpose of this study is to agree a Pressure Ulcer Minimum Data Set (PU-MDS) and develop an evidence based Pressure Ulcer Risk Assessment Framework (PURAF) for use in clinical practice. This information sheet relates to the PU-MDS element of the study.

Why have I been chosen?

You have been invited to be a member of the Nominal Group because of your subject expertise, which is relevant to the assessment or measurement of pressure ulcer risk factors.

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 asking any questions you may have. If you wish to participate you will be asked to provide consent by returning a Word Document with your electronic signature. You will be able to retain a copy of this for your records and one will be held by the researcher. You will be free to withdraw from the study at any time including before, during or after nominal group meetings and before, during or after

questionnaire completion, without giving a reason. Data collected from you prior to withdrawal will be used in the final study analysis. However, if you do not want your existing data from nominal group meetings or completed questionnaires to be used you can inform the researcher and this data will be destroyed and excluded from the study.

What does Nominal Group Membership involve?

If you agree to take part in the study, you will be required attend two meetings over a 12- 18 month period. Standard rate travel expenses will be reimbursed. The meetings will involve 12-14 academic or healthcare experts from a number of countries and will include in-depth discussions and debate about the factors for inclusion in a PU-MDS. Each meeting will last approximately 3.5 hours and will include refreshments and comfort breaks. The meetings will be led by trained facilitators and will be audio-taped and transcribed to allow thematic analysis of the meeting to occur. You will also be required to read a pressure ulcer systematic review summary report, comment on the content of consensus questionnaires and to complete two web-based consensus questionnaires.

Within the questionnaire you will also be asked to provide anonymous demographic data including: age, gender, nationality, area of expertise, role and sector i.e. university, community or acute hospital to allow the nominal group characteristics to be described. The summary report will take approximately 30 minutes to read and each questionnaire will take approximately 15 minutes to complete. Further email and telephone correspondence may also be required.

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 and this may involve you travelling for meetings.

What are the possible benefits of taking part?

You will be contributing to the development of a PU-MDS which will facilitate the interpretation and further use of pressure ulcer research data and meta-analysis. This will contribute to the development of an evidence based PURAF which could lead to improvements in patient care. Nominal group members will be listed as contributors for the main study publication, subject to your agreement. The researcher will write to you prior to

publication to ask you about this. If you agree to this you will be asked to complete a short form indicating that you agree to be listed as a contributor.

Will my taking part be kept confidential?

As part of the nominal group your identity would be apparent to other group members due to the face to face meetings but your questionnaire responses would be anonymised before being presented to the nominal group or being detailed in any reports. Your individual responses would not be revealed by the Clinical Trials Research Unit (CTRU). However, whilst under no obligation to do so, you would be free to share this with the group should you wish to.

All information collected will be handled, processed, stored, and destroyed in accordance with the Data Protection Act 1998. Where personal data is provided this 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 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, 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 have any questions please contact:

Susanne Coleman
PU-MDS and PURAF Project Lead
Clinical Trials Research Unit
University of Leeds
Leeds
LS2 9JT
Tel: 0113 343 4854
Fax: 0113 343 1471
Email: medscole@leeds.ac.uk
Website: www.ctruleeds.co.uk

What do I do now?

If you wish to participate please provide consent by returning the Word Document (attached in the introductory email) with your electronic signature.