UNIVERSITY OF Southampton

Participant Information Sheet

Study Title: Developing a Minimum Data Set and a reporting guideline for Medical Device-Related Pressure Ulcers – A consensus study.

Researcher: Ewa Crunden
ERGO number: 49718

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part. You may like to discuss it with others, but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to confirm consent to take part.

What is the research about?
This study is a part of a larger project undertaken in fulfilment of a Doctor of Philosophy (PhD) degree. I have graduated from University of Southampton BSc (Hons) Healthcare Management, Policy and Research and currently undertaking a PhD in Health Sciences. I am interested in expert international opinion on how medical-device related pressure ulcers should be reported. Currently these wounds are not routinely reported, and the data collected is not standardised across organisations, nationally nor internationally. That means we cannot make any meaningful comparisons or improve prevention of these ulcers. We also do not know explicitly which of the devices cause patient harm, and thus how their design could be improved. Establishing a robust international standard, based on international consensus is the first step in ensuring safe, harm-free patient care.

Why have I been asked to participate?
I am looking to talk to healthcare professionals who have in-depth knowledge of pressure ulcer reporting because of their work, those who are research active academics in the field of pressure ulcers, and representatives of medical device manufacturing companies. You are a member of one of these organisations which brings together professionals with different expertise in the medical device and wound prevention field.

What will happen to me if I take part?
I am inviting you to participate as a panel member of an international consensus study. You will be asked to participate in three rounds of questionnaires (this may be reduced to two, if consensus is reached earlier). Your participation will be completely anonymous, all questionnaires will be sent to you and completed online, and only the researcher will know who participated in this study. There will not be a need to meet with the other participants (the panel) physically.

In the first round you will be presented with findings from a literature review and an interview study, collated into bullet points regarding medical device-related pressure ulcer reporting. You will be asked to rate their appropriateness on a scale from one to nine (1=not relevant, 9=relevant), additionally you will have an opportunity to add any other criteria you think might be important to include. Each subsequent round will be developed based on the results from the preceding round and will consist of a summary of its results i.e. the level of consensus in the panel, and a revised questionnaire. You will be asked to review your responses in the view of the results and repeat the scoring for a maximum of two further rounds.

Completion of the questionnaire in each round should not take longer than 30 minutes. Each round is planned to take four weeks, which included up to thee weeks for the questionnaire to be returned, and a week for the researcher to analyse and report on the results. Participation will be purely online, with email communication and reminders for each task.

Are there any benefits in my taking part?
There is no direct benefit to the participant. However, findings of this study will form the basis for developing of an international standard for reporting medical device pressure ulcers, which if evaluated as successful, could improve the care and safety of patients.

Are there any risks involved?
The questionnaire rounds are expected to be straightforward as they are related to your work and expertise.

What data will be collected?
We will collect basic demographic details, e.g. what country you represent, what is your profession and how long you have been working in your current role. You will be asked to rate a list of recommendations, add any additional recommendations that you may feel are important, or make suggestions for changes in recommendations presented to you. Questionnaire responses will be stored securely on a password protected computer. Personal data collected for the purposes of the study, and non-identifiable data will be kept separate and using encrypted files on a password protected computer.

It is planned that the study will be completed by the end of June 2020, and a report will be sent to all members of the panel.

Will my participation be confidential?
Your participation and the information we collect about you during the course of the research will be kept strictly confidential. You will be assigned a unique identifier on entry to the study, this will be kept separately, to any personal information. Data at all times will be stored securely on a password protected computer. Personal data collected for the purposes of contacting participants and non-identifiable data will be kept separate. Physical copies of returned questionnaires will be stored in a lockable cabinet at the Clinical Academic Facility in Southampton General Hospital.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

Do I have to take part?
No, it is entirely up to you to decide whether or not to take part. If you decide to take part, please email me directly at **eac1g14@soton.ac.uk.**

What happens if I change my mind?
You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected. In such case, please email me directly at **eac1g14@soton.ac.uk.** However, a lack of returned questionnaire will also indicate to me that you have decided to withdraw from the study.
If you withdraw from the study, we will keep the information about you that we have already obtained for the purposes of achieving the objectives of the study only.

What will happen to the results of the research?
This study is a part of a postgraduate research project, in partial fulfilment of Doctor of Philosophy (PhD) degree and will also be written up as a part of PhD thesis and published in a scientific journal. Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

Where can I get more information?
If you have any questions you may have in regard to this study, please contact the main researcher:

Mrs Ewa Crunden
Email: eac1g14@soton.ac.uk

What happens if there is a problem?
If you have a concern about any aspect of this study, you should speak to the researcher who will do her best to answer your questions – see contact details above.
If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

Data Protection Privacy Notice
The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such

information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

Thank you very much for your time!