



## **Usability and Accuracy for a Digital Pain Logging Device**

### **Participant Information Sheet** (Version 1.0, 20/04/2017)

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We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. We suggest that it may take about 5 minutes to read thoroughly. If, after reading this information sheet, you think you may be interested in taking part you will have the opportunity to ask any questions before you agree to anything.

### **Summary**

Given that there is no medical test to directly measure pain, we mainly rely on patient self-reports either in a paper diary or by telling a nurse who writes the answer in a log. This method can result in missing data if patients are not asked regularly or cannot write down their pain level or they forget to fill in the diary. It also results in a slow response as it may be a long time before someone is able to read the pain levels and act on

them. This study involves giving you a small device called a PainPad so you can record your pain levels on your own.

## **What's involved?**

After reading this sheet and having any questions answered, you will be asked to provide your consent to participate in the study. If you agree we will give you a PainPad and ask you to press one button from 0 to 10 to indicate your pain whenever the device beeps. It will only beep between the hours of 8 AM and 10 PM. You can also enter your pain score at any time. If you don't hear the beeping or don't enter a value for any reason don't worry, the box will still beep for you the next time. You will only use the PainPad while you are in hospital and you can stop using it at any time.

We will give you a very short 1 page questionnaire about your experience of using the PainPad and ask that you fill it out before you leave the hospital. During your stay you may also be asked by nursing staff to give your pain level for their records.

## **What are the potential benefits and risks?**

While the immediate benefits of this study to you are limited, the primary benefit of this study, however, is to improve the current process of pain management in hospitals.

There are no foreseeable risks arising from participation in this research and while you will not receive any payment, you will make a vital contribution to pain management research and possibly improving the experience for others.

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

Your participation in the study is entirely **voluntary**, and you can choose to withdraw at any time without giving a reason and this will not affect your care or treatment in any way. You may also ask to have your data deleted at any time, although if we have anonymised your data this may not be possible.

## **How will my information be kept confidential?**

The data collected will only be accessible to the named researchers on this study. Personally identifying information will not be electronically stored with your data. Instead a unique ID will be generated to record your data and we will ensure that you can never be identified by any data we publish.

The data will be retained for up to 5 years after the study. The results of this study may be published in a scientific journal. If you would like to receive the results of the study you can indicate this on the consent form.

## **Who is organising and funding this study?**

This research is in part being supported by a research grant from the Engineering and Physical Sciences Research Council and researchers from both the Open University and Milton Keynes University Hospital.

## **Who has reviewed this study?**

This research has been reviewed and approved by the [REDACTED] Human Research Ethics Committee and has been given a favourable opinion (REF HREC17/XXXXXXX)

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## **Invitation to ask further questions**

Please feel free to ask any member of the researcher team if you have any concerns or questions in relation to this study before agreeing to the Consent Form. You may also ask any questions throughout and after completion of the study.

You can contact the researchers as follows:

[REDACTED]

**Thank you for taking the time to read this information sheet and considering taking part in this study**