Participant Information Sheet for Ward Managers

Study Title: Safer and more efficient vital signs monitoring to identify the deteriorating patient

You are being invited to take part in this 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 in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part.

# What is the research about?

This is part of a larger study with an overall aim to derive a safe, achievable, evidenced-based protocol for monitoring patients’ vital signs on the general hospital wards. This part of the study seeks to provide estimates of the nursing work involved in measuring vital signs, and to understand what might affect differences in the time taken to measure vital signs.

## Why is an evidence-based protocol for monitoring patients’ vital signs needed?

Taking measurements of heart rate, blood pressure, temperature and other “vital signs” is an important part of care for nearly all patients in hospital and is often referred to as taking observations. Changes in observations are used to track recovery and can show when someone’s condition is getting worse and needs urgent attention. When changes are spotted early, medical staff can often prevent serious deterioration, provide early treatment and avoid serious consequences including death. However, taking observations can be burdensome to patients, interfering with rest and sleep, which are also important to recovery. Frequent observations also cause more work for nursing staff. At the moment, there is little evidence to guide hospital staff on how frequently to take observations and there is little evidence to show how much work is involved in taking observations.

## Overall study

Our overall study aims to address this by developing a protocol for how frequently observations should be made. 6 million vital signs measurements from over 200,000 hospital admissions from two hospitals where observations are recorded in electronic systems are available. Using information from one hospital we will calculate NEWS scores and look to see how these change over time, with the aim of identifying the earliest point possible where we might detect that patient deterioration. By linking these measurements to other information (such as diagnoses, cardiac arrests, intensive care admissions), we will also be able to see the extent to which changes in vital signs affect patients’ risk of poor outcomes. The results of these analyses will be used to set monitoring schedules, which will then be tested on the patient data from the second hospital.

Together with the results from the prospective study, where we watch and time ward staff taking observations, we will also be able to estimate how much work will be generated by each monitoring schedule and estimate the expected staff requirements. We aim for this study to provide the first evidenced-based protocol for patient monitoring, which will be both safe and achievable across all acute NHS hospitals.

# Why participate?

The hope is that the research will make a difference by producing observation schedules that avoids unnecessary nursing workload while making sure that observations taken contribute to improved patient safety. In the long term you and staff on your ward and your patients may benefit from this.

# What will happen to me if I take part?

If you agree that you and your staff will take part in the study, we will arrange a further meeting with you where we will discuss the project and get more details about how vital signs observations are organised on your ward. Based on the information you give us, we will organise times for a researcher to come to the ward and watch staff taking vital signs observations. We will ask you to explain the study to your nursing staff and we will also ask permission to put up posters for staff and patients on the wards and provide information sheets for staff and patients.

During scheduled observation times the observer will introduce themselves to the staff and patients on your ward and briefly explain why they are there, what they will be doing and check that staff and patients are happy for care to be observed. The researcher will make records on a tablet computer of the start and finish time, escalation responses and additional factors involved with taking vital observations. Occasionally they may ask brief questions of staff to clarify things. Researchers will not observe intimate care or care behind closed curtains. This will all be recorded anonymously without any identifiable information and stored on an electronic tablet with password- protected access and encryption.

The researcher will not get involved in care and individual members of staff will have the opportunity to opt out if they choose. We do not anticipate that the presence of researchers will alter the way care is delivered in any way, although staff might be asked to alert the researcher when observations are going to be taken. In total, the researcher will be on the ward observing care for approximately 8 hours in 4 sessions of 2 hours each, although with your agreement we may split some 2 hour sessions within the same day.

There are no risks involved in taking part.

# What data will be collected?

During our meeting with you we will record on paper your consent and details profiling your ward. These items will be kept confidentially. The consent is recorded in order that we can keep an audit trail on agreement to participation in the study. The purpose of profiling the ward is to collect contextual and additional factors that may be relevant to inform the accuracy of the results.

During the observations no personal data of nursing staff or patients will be collected. We will record the start and finish time of observations carried out, including additional factors (for example staff type, whether the observations were routine/follow-up or unplanned and whether the observations required escalation or involved specialist neurological or surgical observations). The data will be collected by an observer who is a member of research team and will be recorded on an electronic tablet with password-protected access and encryption.

All data will be handled securely, during collection, analysis, storage and transfer using encryption and password protected access, and lockable cabinets for the ‘consent form’ and ‘ward profile’ paper records data. Only the research team will have access to the data and for the purpose of data analysis and economic evaluation. Original data including your consents will be kept for no more than 10 years although anonymised and non-personal data may be retained for analysis purposes for longer.

# Will my participation be confidential?

Your participation and the information we collect about you and your ward during the course of the research will be kept strictly confidential. Only members of the research team and responsible members of the Universities of Portsmouth and Southampton may be given access to data about you or your ward 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?

It is entirely up to you to decide whether or not you want your ward to take part. We will not seek explicit consent from individual members of your ward team: we will work with you to make sure that they are fully informed and give staff the opportunity to opt out should they wish. We will keep a record of any staff members who choose to opt out.

# 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. Any anonymous data already collected cannot be withdrawn, however we will keep the information that we have already obtained for the purposes of achieving the objectives of the study only.

If you wish to withdraw after you have given consent, please speak to the observer on your ward or email fobs@soton.ac.uk.

# What will happen to the results of the research?

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.

# What happens if sub-optimal or unsafe practice is observed?

In the very unlikely event that the observer witnesses unsafe practice, the observation will be halted and the event reported to hospital management. Other practices that fall short of "best practice", would not be recorded or reported unless they represent incompetence or misconduct, in which case the observer would report this to the individual's manager.

Staff employment rights will not be affected.

# For more information, please contact

Study email: fobs@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 researchers who will do their best to answer your questions. If you remain unhappy about any aspect of this study, please contact the project's chief Investigator: Prof Jim Briggs via email at fobs-contact-group@port.ac.uk or by telephone at 023 9284 6438.

Our sponsor: University of Portsmouth

If you have any concerns relating to Research Integrity at the University of Portsmouth, please contact Professor Bob Nichol, Pro Vice-Chancellor Research and Innovation by email at bob.nichol@port.ac.uk or by telephone at 023 9284 4472.

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NRES: This project was approved by South Central - Berkshire Research Ethics Committee reference number 19/SC/0190

If required, you may pursue a complaint through your Trust's procedure.

# Data Protection Privacy Notice

We conduct research to the highest standards of research integrity. As a publicly-funded organisation, each 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 of Portsmouth is the sponsor for this research. Our data protection policy governing the use of personal data by the University can be found on our website (<https://www.port.ac.uk/about-us/corporate-information/corporate-governance/data-protection>).

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.

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 Portsmouth 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 Portsmouth 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 Portsmouth 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.port.ac.uk/about-us/corporate-information/corporate-governance/data-protection>) where you can make a request using our online form. If you need further assistance, please contact the University’s Data Protection Officer (information-matters@port.ac.uk).

# Thank you

Thank you for taking the time to read the information sheet and considering taking part in the research.