Dear [*Name to be inserted*],

RE: HOSPITAL PATIENT SAFETY—A REALIST ANALYSIS

I am writing to invite you to participate in a research study of hospital patient safety in Wales. *[This study is led by Professor Martin Kitchener, Associate Dean, and Director of Cardiff Healthcare Organisation and Policy Studies (CHOPS) at Cardiff Business School, Cardiff University. It is funded by the National Institute for Health Research Service Delivery and Organisation Programme (NIHR SDO)]

* Latterly revised to:

[This study is led by Professor Martin Kitchener, Dean, Cardiff Business School, Cardiff University. It is funded by the National Institute for Health Research Health Services and Delivery Research Programme (NIHR HS&DR)]

The study aims to examine the local implementation of three safety interventions—(i) *Improving Leadership for Quality Improvement*, (ii) *Reducing Surgical Complications*, and (iii) *Reducing Healthcare Associated Infections*—in NHS hospitals participating in the Welsh *1000 Lives*[+] programme. In so doing, it will address the principal research objective to examine which organisational contextual factors matter, how they matter, and thus explain why they matter in order that the processes and outcomes of hospital patient safety interventions may be improved.

I hope that you wish to participate in this study, and help to promote improvements in patient safety and healthcare quality across NHS Wales. In that hope, I therefore enclose a Participant Information Sheet that sets out further information for your consideration.

Participation in this study will involve an interview (approximately one hour) to discuss your views of the local implementation of the three focal safety interventions selected from the Welsh *1000 Lives* [+] programme, and the organisational factors which impact upon hospital patient safety. Furthermore, as the study progresses, participants will be invited to attend a feedback workshop to comment on its interim and end-stage results.

If you wish to participate in this study, or if you require further details, please do not hesitate to call me on [ ] or e-mail me at [ ].

Yours sincerely,

[redacted]

[redacted]

[redacted]

[redacted]

Tel:

Web site: http://www.cf.ac.uk/carbs/research/hospitalpatientsafety

HOSPITAL PATIENT SAFETY: A REALIST ANALYSIS

[NIHR SDO 10-1007-06]

PARTICIPANT DETAILS

Surname: _____

First name(s): _____

Organisation: _____

Job title: _____

Date: _____

FOR STUDY USE ONLY

INTRODUCTION

This study aims to examine the local implementation of three safety interventions—(i) *Improving Leadership for Quality Improvement*, (ii) *Reducing Surgical Complications*, and (iii) *Reducing Healthcare Associated Infections*—in NHS hospitals participating in the Welsh *1000 Lives*$^{+}$ programme.

In doing so, it will address the principal research objective to examine which organisational contextual factors matter, how they matter, and thus explain why they matter in order that the processes and outcomes of hospital patient safety interventions may be improved.

STUDY OBJECTIVES

The proposed study has five main research objectives.

1. To identify and analyse the organisational factors (e.g., structure, culture, and managerial priorities) pertinent to the health outcomes of hospital patient safety interventions.
2. To identify and analyse the contextual mechanisms (logics, or belief systems) that interact with organisational factors to generate the health outcomes of hospital patient safety interventions.
3. To develop and test hypotheses concerning relationships between organisational factors, mechanisms, and the health outcomes of hospital patient safety interventions.
4. To produce a theoretically-grounded and evidence-based model of which organisational factors matter, how they matter, and why they matter.
5. To establish and disseminate lessons for a broad range of stakeholders concerned with patient safety policy and management.

THE ROLE OF PARTICIPANTS

Participation in this study will involve an interview (approximately one hour) to discuss your views of the local implementation of the three focal safety interventions selected from the Welsh *1000 Lives*$^{+}$ programme, and organisational factors which impact upon hospital patient safety.

INVITATION TO PARTICIPATE IN THIS STUDY

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. **One of our team will go through the information sheet with you and answer any questions you have.** We suggest this should take at least 10 minutes.

Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear.

PART 1

WHAT IS THE PURPOSE OF THE STUDY?

It is estimated that one in ten National Health Service (NHS) hospital patients are harmed during their care, and one in 300 die as a result of adverse events. Along with these human costs, safety incidents are a drain on devolved NHS resources, costing an estimated £3.5 billion a year in additional bed days and negligence claims.

As awareness grows about the systematic nature, scope, and costs of these problems, patient safety has been driven to the top of the NHS agenda, and numerous improvement programmes have been introduced. However, evidence that the outcomes of NHS patient safety improvement programmes vary across hospitals demonstrates that the organisational context of their implementation matters. Yet the relationships between features of organisational context (e.g., structure, culture, and managerial priorities) and the health outcomes of patient safety programmes are both under-theorized and poorly understood in empirical terms.

The study, **Hospital Patient Safety: A Realist Analysis**, is the first to employ insights from institutional theory (concerning the role of competing views, or 'logics' as mechanisms for change and resistance) within an innovative approach (realist analysis) to the study of patient safety research. The main aim is to examine which organisational contextual factors matter, how they matter, and thus explain why they matter in order that the processes and outcomes of hospital patient safety interventions may be improved.

WHY HAVE I BEEN INVITED?

During this study, the research team will collect available documents containing organisational and clinical improvement data related to the local implementation of the three safety interventions selected from the Welsh *1000 Lives*$^{+}$ programme: (i) *Improving Leadership for Quality Improvement*, (ii) *Reducing Surgical Complications*, and (iii) *Reducing Healthcare Associated Infections*. However, this information will be supplemented by extensive fieldwork at each participating Welsh NHS Hospital, including interviews with a broad range of hospital staff:

(i) *Executive Board*—Chair, Chief Executive, Board Secretary, and Board Directors (Finance; Human Resources, Workforce and Organisational Development; Medicine; Nursing; Planning, Performance and Delivery; Therapies and Health Sciences);

(ii) *Senior-Middle Corporate and Clinical Management*—Chief Pharmacist, Consultants (Anaesthetist, General Medicine, Microbiology and Infection Control, and General Surgery), Directorate Managers (General Medicine, Operating Theatres, Recovery and Anaesthetics, Surgery), and hospital leads for: Risk Management, Clinical Governance, Clinical Coding, Patient Advice and Liaison, Litigation and Complaints Management;

(iii) *Clinical Arena* (1): *Operating Theatres, Recovery, Ward Departure and Return*—Consultant Nurse (Surgery Assistant), Junior Doctors (Anaesthetist, General Surgery), Operating Department Practitioner, Radiographer, Theatre Sister

(Operating Theatres, Recovery and Anaesthetics), Ward Sisters (General Medicine, Surgery, and Intensive Therapy Unit/High Dependency Unit);

(iv) *Clinical Arena* (2): *Infection Control*—Consultant Nurse (Infection Control), Junior Doctors (Elderly Care Medicine, General Medicine, Paediatrics and Neonatology, and Renal Medicine), Specialist Clinical Pharmacist (Antibiotic Management and Infection Control), Ward Sisters (Elderly Care Medicine, General Medicine, Paediatrics and Neonatology, and Renal Medicine).

In addition, this data will be complemented by interviews undertaken with consumer champions and representatives of external bodies, including: policy-makers, the National Patient Safety Agency, and the Health Foundation.

In this study, we therefore seek your views of the local implementation of the three focal safety interventions selected from the Welsh *1000 Lives*$^{+}$ programme, and your opinion of the organisational factors which impact upon hospital patient safety.

All data collected in this manner will be treated as confidential and anonymised (at the individual, site hospital and organisational level). The only person identifiable data collected during this study will be: (i) participant's names; (ii) their organisational role; and (iii) employing organisation. This data will be held within the proposed study's anonymisation record, which will be stored in a locked filing cabinet in Cardiff Business School. All hard copy archive and anonymised data will be stored in a locked filing cabinet in Cardiff Business School, and accessible only by the research team. All electronic raw data files will be password protected and accessible only by the research team.

DO I HAVE TO TAKE PART?

Your participation in this study is entirely voluntary and unpaid. You are free to withdraw at any time, without giving a reason.

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

The Senior Research Fellow working in this study will contact you, via letter or e-mail, to arrange a suitable date and time for you to be interviewed. This one-hour interview will normally occur in your employing organisation.

It is anticipated that most participants will be interviewed once. However, key individuals who offer a great depth of insight into the focal areas of the study, will be approached to undertaken a follow-up interview.

As the study progresses, you will be invited to attend a feedback workshop to comment on its interim and end-stage results.

Throughout this study, contact may be maintained via the study's dedicated web site: [www.cf.ac.uk/carbs/research/hospitalpatientsafety], and a specific e-mail contact address [ ].

WHAT WILL I HAVE TO DO?

In this study, we are seeking your views of the local implementation of the three focal safety interventions selected from the Welsh *1000 Lives*$^{+}$ programme, and your opinion of the organisational factors which impact upon hospital patient safety.

You will be asked to reflect upon our questions, and answer only those that you want to—*there are no right or wrong answers.* However, your opinion is very important to this study. All you have to do is express your beliefs and understanding of hospital patient safety.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

This study poses a very low risk, or burden, to potential research participants. However, participant will experience:

(i) minimal intrusion during the process of seeking their consent to participate in the study;

(ii) limited disruption to their routine working day, incurred through the face-to-face or telephone interview process, which will last up to one hour;

(iii) assured anonymity, and

(iv) complete confidentiality.

Your inconvenience will be minimised by arranging interviews well in advance.

WHAT IF THERE IS A PROBLEM?

Any complaint about the way you have been dealt with during the study will be addressed. The detailed information on this is given in Part 2.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

The study presents all its research participants with an opportunity to express their beliefs and understanding of hospital patient safety, and specifically the organisational factors which impact upon the local implementation of the three focal patient safety interventions selected from the *1000 Lives*$^{+}$ programme: (i) improving leadership, (ii) reducing hospital acquired infection rates, and (iii) implementing surgical checklists.

Given that the relationships between features of organisational context (e.g., structure, culture, and managerial priorities) and the health outcomes of patient safety programmes are both under-theorized and poorly understood in empirical terms, the information offered by participants is essential to further inform the design of such patient safety initiatives. Therefore, following collation of the study's findings, its research participants—amidst others in the broader healthcare organisational and policy field—will, ultimately, benefit from the roll-out of new patient safety initiatives which are designed to reflect local constraints, challenges, and inherent strengths.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details of this are included in Part 2.

This concludes Part 1.

PART 2

WHAT IF THERE IS A PROBLEM?

If you have a concern about any aspect of this study, you should ask to speak to the researcher team's Chief Investigator, Professor Martin Kitchener, who will do his best to answer your questions.

Professor Kitchener may be contacted by telephone on [redacted] or via e-mail ([redacted].

If you remain unhappy and wish to complain formally, contact the [redacted]

CONFIDENTIALITY

Participants' anonymity will be assured throughout this study. Each participant, hospital site, interview transcription, and researcher, will be assigned an identity code. (The study's Senior Research Fellow will undertake the anonymisation of all data.) One source of person-identifiable information—the anonymisation record stating the participant's name, role, employing organisation, and corresponding identification code—will be held as a paper record, and stored in a locked filing cabinet in Cardiff Business School. This information will only be accessible to the research team. No further person-identifiable information will be stored in the form of a paper document.

An electronic version of the anonymisation record will be stored on the study's dedicated shared drive within Cardiff University. Access to this drive will be restricted to the research team. No further person-identifiable information will be stored in the form of an electronic record. All anonymised electronic raw data files—and collated, anonymised, and analysed data—will be password protected, and accessible only by the research team. The electronic transfer of data within the UK (via email or computer networks) between the research team will consist of anonymised and encrypted data. This data will be shared with the explicit proviso that

the recipients cannot: (i) disclose the data to third parties; or (ii) link the data with other data, which may render the information more identifiable.

The publication of direct quotations from the study's participants will be anonymised at the individual, hospital site and organisational level. Hence, no combination of incidental details of the participant's employing organisation, specific role, age or ethnicity will be reported, thereby ensuring individuals remain unidentifiable.

The study's research data will be stored for at least two years post publication of the end stage report, in accordance with Cardiff University's Research Ethics and Governance Guidelines for research records management.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

During the study, half-day interim workshops will be held to check data, feedback initial findings and elicit further comments from invited participants. In addition, our findings will be disseminated to user communities through articles in practitioner journals, and presentations to research forums.

In the final year of the study, knowledge transfer will take place through a half-day final seminar to test the implications of key findings, plus a national, one-day dissemination conference in Cardiff for senior policymakers and practitioners across the UK.

Furthermore, a project website will be created at the outset of the project. This will contain project reports and updates, academic articles, conference papers, and other material publicising our findings. The website will also incorporate an interactive bulletin board dedicated to the study that will provide a further means of establishing a dialogue with stakeholders and participants. In order to maximise use of the site we will publicise it through the workshops, conferences and short reports that we produce and publish.

The academic dissemination of our empirical findings at the main patient safety and health research conferences, and in the highest ranked journals, will ensure impact

among relevant academic communities.

WHO IS ORGANISING THE FUNDING OF THE RESEARCH?

This study is funded by the National Institute for Health Research Service Delivery and Organisation Programme (NIHR SDO), managed by NETSCC, SDO, as part of the NIHR Evaluation, Trials and Studies Coordinating Centre at the University of Southampton.

National Institute for Health Research
Service Delivery and Organisation Programme
Alpha House
University of Southampton Science Park
Southampton
SO16 7NS
sdofund@southampton.ac.uk

WHO HAS REVIEWED THE STUDY?

As the funding organisation, the Commissioning Board of the National Institute for Health Research, Service Delivery and Organisation (NIHR SDO) programme, has undertaken a comprehensive two-stage (outline and full proposal) expert peer review and assessment of the scientific quality of the proposed research.

Furthermore, prior to submission to the NIHR SDO, the research study was subject to internal peer review in Cardiff Business School, and across the wider research team located within the National Institute for Social Care and Health Research (NISCHR), Patient Safety and Healthcare Quality Registered Research Group, at the School of Medicine, Cardiff University, and Nottingham University. The research protocol, provisional questionnaire, and consent form have been approved by the Research Ethics Committee in Cardiff Business School, and by the Main Research Ethics Committee for Wales.

RESEARCH TEAM AND CONTACT DETAILS

For further information about the research, and advice about participation, please contact the Chief Investigator.

CHIEF INVESTIGATOR

Professor Martin Kitchener BSc(Econ) MBA PHD

[redacted]

Professor Jonathon Gray BMSc MBChB PhD MPH

[redacted]

Dr Justin Waring BA MSc PhD

[redacted]

Dr Andrea Herepath PhD MBA PhD

[redacted]

HOSPITAL PATIENT SAFETY: A REALIST ANALYSIS

[NIHR SDO 10-1007-06]

PARTICIPANT DETAILS

Surname: _____

First name(s): _____

Organisation: _____

Job title: _____

Date: _____

FOR STUDY USE ONLY

YOUR CONSENT TO PARTICIPATE IN THIS STUDY

Case site code: _____

Participant code: _____

1. I confirm that I have read and understand the Participant Information Sheet dated: [_____] [version: _____] for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation in this study is voluntary and that I am free to withdraw at any time without giving any reason. ☐

3. I understand that my participation in this study in this study will involve an interview to discuss the local implementation of the three focal safety interventions selected from the Welsh *1000 Lives Plus* programme, and my opinion of the organisational factors which impact upon hospital patient safety, which will require approximately one hour of my time. ☐

4. I consent to audio-taping, and the possible use of verbatim quotations which will be anonymised. ☐

5. I understand that the information provided by me will be held securely in Cardiff University. I understand that, in accordance with the Data Protection Act (1998), this information may be retained indefinitely. ☐

6. I agree to take part in the above study. ☐

Name of participant: **Date:** **Signature:**

_____ _____ _____

Name of person taking consent: **Date:** **Signature:**

Name of researcher:	**Date:**	**Signature:**