Health Research Authority
NRES Committee South West - Central Bristol
Whitefriars
Level 3, Block B
Lewin's Mead
Bristol BS1 2NT
Email: nrescommittee.southwest-bristol@nhs.net

Telephone: 0117 342 1335
Fax:0117 342 0445

13 April 2015

Dr Colin Powell
Senior Lecturer in Child Health and Honorary Consultant Paediatrician
Cardiff University
Dept of Child Health
School of Medicine,
Heath Park, Cardiff
CF14 4XN

Dear Dr Powell

Study title:	**PUMA - Paediatric early warning system (PEWS): Utilisation and Mortality Avoidance. A prospective, mixed methods, before and after study identifying the evidence base for the core components of an effective PEWS and the development of an implementation package for implementation and use in the UK.**
REC reference:	**15/SW/0084**
Protocol number:	**SPON1362-14**
IRAS project ID:	**156458**

The Research Ethics Committee reviewed the above application at the meeting held on 27 March 2015. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Mrs Naazneen Nathoo, nrescommittee.southwest-bristol@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

1. The participant information sheets should quote the name of our Committee as "NRES Committee South West – Central Bristol REC". It should be ensured that the consent form/s quote the correct version number and date of the PIS.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

The sponsor is asked to provide the Committee with a copy of the notice from the MHRA, either confirming no objection or giving grounds for objection, as soon as this is available.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Summary of discussion at the meeting

- **Social or scientific value; scientific design and conduct of the study**

  It was unclear whether results would make a difference as these would be a composite outcome. Some outcomes could go up whilst other could go down: members queried whether this would cancel each other.
  You advised you were aware of this and would look out for such data.

- **Recruitment arrangements and access to health information, and fair participant selection**

  It was noted that individuals could opt out of being observed and no notes would be taken. It was unclear to members how this would be managed if a lot of people on the ward opted out.
  You replied you would like to think this would not happen. If the Trust was supportive, most people would participate. This was about improving outcomes for children.

  Upon query, you confirmed that observation would be undertaken during, and out of hours, at weekends and Bank Holidays.

Other ethical issues were raised and resolved in preliminary discussion before your attendance at the meeting.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [PUMA Poster - Observations]	v1.0	01 March 2015
Copies of advertisement materials for research participants [PUMA Poster - Parent Interview]	v1.0	01 March 2015
Covering letter on headed paper [PUMA Ethics Cover Letter]		09 March 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Employer's Public Liability]		30 July 2014
Interview schedules or topic guides for participants [TOPIC GUIDE STAFF INTERVIEWS PRE-IMPLEMENTATION]	v1.0	01 March 2015
Interview schedules or topic guides for participants		

Interview schedules or topic guides for participants [Ethnographic fieldwork observations template]	v1.0	01 March 2015
IRAS Checklist XML [Checklist_09032015]		09 March 2015
Letter from funder [NIHR HS&DR Funding letter]		10 October 2014
Letter from sponsor [20150306 SPON1362-14 Powell C]		06 March 2015
Participant consent form [PUMA Consent Form (Shadowing Staff)]	v1.0	01 March 2015
Participant consent form [PUMA Consent Form (Staff interviews)]	v1.0	01 March 2015
Participant consent form [PUMA Consent Form (Parent interviews)]	v1.0	01 March 2015
Participant information sheet (PIS) [PUMA PIS - general ethnography (observations)] ***	v1.0	01 March 2015
Participant information sheet (PIS) [PUMA PIS - Staff Interviews]***	v1.0	01 March 2015
Participant information sheet (PIS) [PUMA PIS - Parent Interviews]***	v1.0	01 March 2015
Participant information sheet (PIS) [PUMA PIS - Staff Information Sheet (shadowing)] ***	v1.0	01 March 2015
Participant information sheet (PIS) [Parent Flyer]***	v1.0	03 March 2015
REC Application Form [REC_Form_09032015]		09 March 2015
Research protocol or project proposal [PUMA Protocol]	v1.0	01 March 2015
Summary CV for Chief Investigator (CI) [Colin Powell CV (short)]	1.0	
Summary, synopsis or diagram (flowchart) of protocol in non technical language [PUMA FlowChart]	v1.0	03 March 2015

***See above.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

15/SW/0084	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

pp. Dr Pamela Cairns
Chair

E-mail: nrescommittee.southwest-bristol@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: *Dr Emma Thomas-Jones, Cardiff University*
Dr Jane Jones, Cardiff and Vale University Health Board

NRES Committee South West - Central Bristol
Attendance at Committee meeting on 27 March 2015

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Kay Barnard	Ex-research scientist	No	
Dr Robert Beetham	Retired Consultant Clinical Biochemist	Yes	
Dr Pamela Cairns (Chair)	Consultant Neonatologist	Yes	
Dr Simon Croxson	Consultant Physician	Yes	
Dr Ian Davies	Consultant in Cardiac Anaesthesia & Intensive Care	Yes	
Mr Alexander Howard	Humanist Funeral Celebrant	Yes	
Dr Adrian Kendrick	Consultant Clinical Scientist	No	
Mr Paul Lewis	Patient Involvement Coordinator	No	
Mr Brian Pixton	Retired solicitor	Yes	
Dr Colette Reid	Consultant in Palliative Medicine	Yes	
Dr Margrid Schindler	Consultant Senior Lecturer	No	
Dr Julie Woodley	Senior Lecturer/ Chair of Faculty Ethics Committee	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Jane Makin	Observer (Senior Administrator, R&D)
Ms Joanna Morris	Observer (R&D, Asstn. Clinical Studies Officer)
Mrs Naazneen Nathoo	REC Manager
Ms Marie Norton	Observer (Research Governance and Office Facilitator)

Written comments received from:

Name	*Position*
Dr Margrid Schindler	Consultant Senior Lecturer