NHS
Health Research Authority

London - City & East Research Ethics Committee
Bristol Research Ethics Committee Centre
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Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

16 March 2017

Prof Heather Elphick
Consultant in Paediatric Respiratory Medicine
Sheffield Children's NHS Foundation Trust
Western Bank
Sheffield
S10 2TH

Dear Prof Elphick

Study title:	**PAEDIATRIC OXIMETRY ALGORITHMS – NORMATIVE DATA COLLECTION**
REC reference:	**17/LO/0483**
IRAS project ID:	**222270**

The Proportionate Review Sub-committee of the London - City & East Research Ethics Committee reviewed the above application on 28 March 2017.

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 hra.studyregistration@nhs.net outlining the reasons for your request. 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

On behalf of the Committee, the sub-committee 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 REC favourable opinion is subject to the following conditions being met prior to the start of the study.

- *Participant Information Sheets should mention that the study has been reviewed by London City & East NHS research Ethics Committee.*

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make 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 must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk 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 management permissions 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 the HRA. Guidance on where to register is provided on the HRA website.

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

The favourable opinion applies to all NHS sites 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").

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Contract/Study Agreement [Sub-contract]	1	28 February 2017
Covering letter on headed paper [REC covering letter]	1	02 March 2017
Instructions for use of medical device [222270 device instructions]	1	01 April 2010
IRAS Application Form [IRAS_Form_02032017]		02 March 2017
Letter from funder [Funding Letter]	1	03 November 2016
Other [Researchers response to HRA request for clarifications]		12 March 2017
Participant consent form [222270 Assent form]	1	10 January 2017
Participant consent form [222270 Parent consent form]	1	10 January 2017
Participant information sheet (PIS) [222270 Parent/guardian information sheets]	1	10 January 2017
Participant information sheet (PIS) [222270 Young persons information sheet]	1	10 January 2017
Participant information sheet (PIS) [222270 Participant information sheet ages 6-12 years]	1	10 January 2017
Participant information sheet (PIS) [222270 Participant information sheet under 6 years old]	1	10 January 2017
Research protocol or project proposal [222270 Viamed protocol]	1	06 January 2017
Summary CV for Chief Investigator (CI) [Heather Elphick CV]	1	26 January 2017

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.
There were no declarations of interest

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

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 HRA 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/

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

17/LO/0483	**Please quote this number on all correspondence**

Yours sincerely

pp Dr John Keen
Chair

Email: nrescommittee.london-cityandeast@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

"After ethical review – guidance for researchers"

Copy to: *Ms Jane Pearson*
Mrs Wendy Swann, Sheffield Children's NHS Foundation Trust

London - City & East Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting in correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr John Keen	GP (REC Chairman)	Yes	
Mr John Lynch	Non - NHS & Voluntary Sector Activity	Yes	
Dr Kieran McCafferty	Nephrologist Consultant/ Hon Senior Lecturer	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Rajat Khullar	REC Manager