Health Research Authority
NRES Committee West Midlands - South Birmingham
Royal Standard Place
Nottingham
NG1 6FS

Tel: 0115 883 9428

15 September 2015

Professor Neena Modi
Professor of Neonatal Medicine
Imperial College London, Section of Neonatal Medicine
4th Floor, Lift Bank D
Chelsea and Westminster Hospital campus
London
SW10 9NH

Dear Professor Modi

Study title:	**eNewborn: European Neonatal Benchmarking and Evaluation Programme**
REC reference:	**15/WM/0344**
IRAS project ID:	**185457**

The Proportionate Review Sub-committee of the NRES Committee West Midlands - South Birmingham reviewed the above application on 15 September 2015.

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 Assistant Nicola Kohut, nrescommittee.westmidlands-southbirmingham@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

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

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 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").

Summary of discussion at the meeting

The PR Sub-Committee agreed that this was a well presented study with no material ethical issues.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		
IRAS Checklist XML [Checklist_07092015]		07 September 2015
Letter from sponsor	1	01 September 2015
Letters of invitation to participant [Invitation to participate with version date]		
Other [Data items in study]	1	31 July 2015
Other [Data transfer agreement]	1	31 July 2015
Participant consent form	1	31 July 2015
REC Application Form [REC_Form_04092015]		04 September 2015
Research protocol or project proposal	1	31 July 2015
Summary CV for Chief Investigator (CI)	1	14 December 2013

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.

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.

15/WM/0344	**Please quote this number on all correspondence**

Yours sincerely

Dr John David Cochrane
Chair

Email: nrescommittee.westmidlands-southbirmingham@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 Becky Ward*

Mrs Doris Daby, Chelsea & Westminster NHS Foundation Trust

NRES Committee West Midlands - South Birmingham

Attendance at PRS Sub-Committee of the REC meeting on 15 September 2015

Committee Members:

Name	*Profession*	*Present*	*Notes*
Ms Philippa Burgon	Lay Member	Yes	
Rev'd Dr Barry Clark	Retired Hospital Chaplain	Yes	
Dr John David Cochrane (Chair)	Retired GP	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Nicola Kohut	REC Assistant