



**National Research Ethics Service**  
NRES Committee London - Dulwich

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28 September 2011

Professor Neena Modi  
Professor of Neonatal Medicine, Imperial College London  
Imperial College  
Room G4.02  
Chelsea & Westminster Hospital  
369 Fulham Road, London  
SW10 9NH

Dear Professor Modi,

**Study title:** The National Neonatal Collaborative Necrotising Enterocolitis Study: Using operational clinical data captured electronically at the point of care for surveillance and research.

**REC reference:** 11/LO/1430

**Protocol number:** CRO1531

The Research Ethics Committee reviewed the above application at the meeting held on 21 September 2011. Thank you for attending to discuss 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.

### **Ethical review of research sites**

#### **NHS 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" below).

#### **Non NHS sites**

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

## 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*

**It is 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).**

## Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		17 August 2011
Investigator CV		
Letter from Sponsor		17 August 2011
Other: Student CV: Cheryl Battersby		17 August 2011
Protocol		18 August 2011
REC application		

## Membership of the Committee

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

## Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) 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 NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

### Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

**11/LO/1430**

**Please quote this number on all correspondence**

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

Yours sincerely,



*P.P.* **Dr David Jewitt**  
**Chair**

Email: [Alene.Pointon@imperial.nhs.uk](mailto:Alene.Pointon@imperial.nhs.uk)

*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: Ms Becky Ward*  
[becky.ward@imperial.ac.uk](mailto:becky.ward@imperial.ac.uk)

*Mrs Mary Anne Tourette*  
*Chelsea & Westminster Healthcare NHS Trust*  
[Mary.Tourette@chelwest.nhs.uk](mailto:Mary.Tourette@chelwest.nhs.uk)

**NRES Committee London - Dulwich**

**Attendance at Committee meeting on 21 September 2011**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Colin Ball	Consultant Paediatrician	Yes	
Dr Will Bernal	Consultant Liver Intensivist	No	
Mr Kai Loke Chan	Assistant Director of Pharmacy	Yes	
Ms Madeleine Colvin	Barrister	No	
Dr Nora Donaldson	Head of Clinical Research Statistics	No	
John Fowler	Lay Member	Yes	
Professor John Garrett	Professor Emeritus, Oral Pathology	No	
Dr Patrick Gordon	Consultant Rheumatologist	Yes	
Dr David Jewitt	Consultant Cardiologist	Yes	
Mrs Carole Jordan	Senior Nurse	Yes	
Dr Thomas Kabir	MHRN Service Users in Research Coordinator	Yes	
Mr Enock Khoromana	Stroke Research Coordinator	No	
Dr Mike Philpot	Consultant Old Age Psychiatrist	No	
Mrs Alene Pointon	Coordinator	Yes	
Ms Anna Ramberg	Research Development Manager	Yes	
Mr Krzysztof Rutkowski	Research Nurse	Yes	
Ms Catherine Walton	Consultant Midwife	Yes	

**Written comments received from:**

<i>Name</i>	<i>Position</i>
Dr Will Bernal	Consultant Liver Intensivist
Ms Madeleine Colvin	Barrister