



Health Research Authority

London - Central Research Ethics Committee

3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ

12 May 2017

Professor Rupert Pearse
Professor of Intensive Care Medicine
Queen Mary University of London
Adult Critical Care Unit, Royal London Hospital
London
E1 1BB

Dear Professor Pearse

Study title: Prevention of Respiratory Insufficiency after Surgical Management (PRISM) Trial: A pragmatic randomised controlled trial of continuous positive airway pressure (CPAP) to prevent respiratory complications and improve survival following major abdominal surgery

REC reference: 15/LO/1595

Protocol number: 10443

Amendment number: Substantial Amendment 2

Amendment date: 13 April 2017

IRAS project ID: 183040

This amendment consisted of minor updates to the Protocol.

The above amendment was reviewed by the Sub-Committee held by correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The sub-committee had no ethical concerns regarding this amendment.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper		13 April 2017
Notice of Substantial Amendment (non-CTIMP)		13 April 2017
Research protocol or project proposal [Changes Tracked]	1.6	10 April 2017
Research protocol or project proposal [Clean]	1.6	10 April 2017
Research protocol or project proposal [Tracked]	1.6	10 April 2017

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

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.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

15/LO/1595:	Please quote this number on all correspondence
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Yours sincerely



pp
Dr Andrew Hilson
Chair

E-mail: NRESCommittee.London-Central@nhs.net

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

*Copy to: Dr Sally Burtles, Barts Health NHS Trust
Mari-Liis, Critical Care Research Office Adult Critical Care Unit The Royal London Hospital*

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Attendance at Sub-Committee of the REC meeting on 08 May 2017

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr Clive Carsley	Retired Lawyer	Yes	Vice Chair
Dr Andrew Hilson	Consultant in Nuclear Medicine	Yes	Chair

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Julie Acourt	REC Assistant