



Health Research Authority

London - Central Research Ethics Committee

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24 April 2016

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: Amendment 1

Amendment date: 01 March 2016

IRAS project ID: 183040

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

Amendment: Changes to the protocol.

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.

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 | | 08 April 2016 | |
| Notice of Substantial Amendment (non-CTIMP) | Amendment 1 | 01 March 2016 | |

| | | | |
|--|-----|---------------|--|
| Research protocol or project proposal [Summary of Changes] | 1.5 | 01 March 2016 | |
| Research protocol or project proposal [Clean] | 1.5 | 01 March 2016 | |
| Research protocol or project proposal [Tracked] | 1.5 | 01 March 2016 | |

Membership of the Committee

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

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

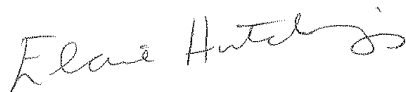
Statement of compliance

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 NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

| | |
|--------------------|---|
| 15/LO/1595: | Please quote this number on all correspondence |
|--------------------|---|

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, Queen Mary University
Mr Richard Haslop, Queen Mary University of London*

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Members of the Committee taking part in the review

Committee Members:

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

Also in attendance:

| <i>Name</i> | <i>Position (or reason for attending)</i> | |
|--------------------|---|--|
| Elaine C Hutchings | REC Manager | |