



Health Research Authority

London - Central Research Ethics Committee

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13 April 2016

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

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

Summary: Changes to the protocol

Thank you for submitting the above amendment, which was received on 08 April 2016. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

Documents received

The documents to be reviewed are as follows:

<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

Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

R&D approval

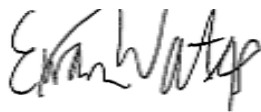
All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval for the research.

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



Ewan Waters
REC Assistant

Email: NRESCommittee.London-Central@nhs.net

Copy to:

Dr Sally Burtles, Queen Mary University
Mr Richard Haslop, Queen Mary University of London