

## **London - Central Research Ethics Committee**

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

04 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

Thank you for submitting the above amendment, which was received on 25 April 2017. 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:

Document	Version	Date
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

## 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 Research Ethics Service Committee members' training days – see details at <a href="http://www.hra.nhs.uk/hra-training/">http://www.hra.nhs.uk/hra-training/</a>

15/LO/1595:

Please quote this number on all correspondence

Yours sincerely

Julie Acourt REC Assistant

Email: NRESCommittee.London-Central@nhs.net

Copy to: Dr Sally Burtles, Barts Health NHS Trust

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