

London - Central Research Ethics Committee

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16 November 2015

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 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

IRAS project ID: 183040

Thank you for your submission of the above study. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 02 October 2015

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Participant information sheet (PIS) [Clean]	1.1	13 October 2015
Participant information sheet (PIS) [Tracked]	1.1	13 October 2015

Approved documents

The final list of approved documentation for the study is therefore as follows:

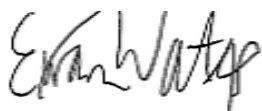
<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [PRISM REC Cover Letter]		20 August 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [QM Clinical Trials insurance]		16 July 2015
GP/consultant information sheets or letters [PRISM GP letter]	1.0	02 July 2015
Instructions for use of medical device [CPAP SOP]	1.0	22 June 2016
Letter from funder [AAGBI funding letter]		12 March 2015
Letter from sponsor [Provisional Sponsorship Letter 24-08-2015]		24 August 2015
Other [Additional information re. study sites and patient information sheet]		02 September 2015
Other [Email with details of questionnaire]		14 September 2015
Participant consent form [PRISM ICF]	1.2	19 August 2015
Participant information sheet (PIS) [PRISM Patient Information Sheet (short)]	1.0	29 June 2015
Participant information sheet (PIS) [Clean]	1.1	13 October 2015
Participant information sheet (PIS) [Tracked]	1.1	13 October 2015
REC Application Form [REC_Form_25082015]		25 August 2015
Referee's report or other scientific critique report [PRISM peer review form]		23 April 2015
Research protocol or project proposal [PRISM protocol]	1.4	18 August 2015
Summary CV for Chief Investigator (CI) [Professor Rupert Pearse CV]		10 January 2015
Validated questionnaire [EQ-5D-3L]		

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

15/LO/1595

Please quote this number on all correspondence

Yours sincerely



Ewan Waters
REC Assistant

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Copy to: Mr Richard Haslop, Queen Mary University of London

Dr Sally Burtles, Queen Mary University