



Health Research Authority

South Central - Oxford C Research Ethics Committee

Health Research Authority (Bristol)
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Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

09 April 2021

Professor Daniel Martin
Professor of Perioperative and Intensive Care Medicine
University of Plymouth
John Bull Building
Derriford
Plymouth
PL6 8BU

Dear Professor Martin

Study title:	Evaluating the clinical and cost-effectiveness of a conservative approach to oxygen therapy for invasively ventilated adults in intensive care.
REC reference:	20/SC/0423
Protocol number:	01/10/20
Amendment number:	SA001
Amendment date:	26 March 2021
IRAS project ID:	288506

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

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [Amendment Tool]	v1.4	26 March 2021
Copies of materials calling attention of potential participants to the research [Information Leaflet (Tracked)]	1.1	19 March 2021
Copies of materials calling attention of potential participants to the research [Information Leaflet]	1.1	19 March 2021
Covering letter on headed paper [Substantial amendment 1 cover letter]	N/A	19 March 2021
Other [Patient Newsletter (Tracked)]	1.1	19 March 2021
Other [Patient Newsletter]	1.1	19 March 2021
Participant information sheet (PIS) [Nominated Consultee Information Sheet (Tracked)]	1.2	19 March 2021
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Participant information sheet (PIS) [Patient Information Sheet (Tracked)]	1.2	19 March 2021
Participant information sheet (PIS) [Patient Information Sheet]	1.2	19 March 2021
Participant information sheet (PIS) [Personal Consultee Information Sheet (Tracked)]	1.2	19 March 2021
Participant information sheet (PIS) [Personal Consultee Information Sheet]	1.2	19 March 2021
Research protocol or project proposal [UK-ROX Trial Protocol]	1.2	19 March 2021
Research protocol or project proposal [UK-ROX Trial Protocol (Tracked)]	1.2	19 March 2021

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.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

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.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

IRAS Project ID - 288506:

Please quote this number on all correspondence

Yours sincerely

A handwritten signature in black ink, appearing to read 'P. P. Potiphar', with a stylized flourish underneath.

**Dr Lee Potiphar
Chair**

E-mail: oxfordc.rec@hra.nhs.uk

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

Copy to: Mr Alvin Richards-Belle, Intensive Care National Audit & Research Centre (ICNARC)

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Attendance at Sub-Committee of the REC in correspondence

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Nicholas Coupe	PhD Student	Yes	
Mrs Vivienne Laurie	Barrister	Yes	Chair of Sub-Committee meeting

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Theodora Chortara	Approvals Administrator