



Health Research Authority

South Central - Oxford C Research Ethics Committee

Health Research Authority (Bristol)
Ground Floor, Temple Quay House, 2 The Square
BS1 6PN

Tel: 0207 104 8241

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.

23 August 2021

Professor Daniel Martin
University Hospitals Plymouth NHS Trust
Critical Care Department
Derriford Hospital
PL6 8DH

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: SA002

Amendment date: 27 July 2021

IRAS project ID: 288506

The above amendment was reviewed at the meeting of the Sub-Committee held on 06 August 2021.

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>
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Completed Amendment Tool [Amendment Tool]	1.5	27 July 2021
Other [Thank you card]	1.0	09 July 2021
Other [Patient Follow-up Letter (tracked)]	1.2	09 July 2021
Other [Patient Follow-up Letter]	1.2	09 July 2021
Research protocol or project proposal [UK-ROX Trial Protocol (tracked)]	1.3	15 July 2021
Research protocol or project proposal [UK-ROX Trial Protocol]	1.3	15 July 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
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Yours sincerely



PP
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 meeting on 06 August 2021

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Lee Potiphar	Senior Lecturer in Adult Nursing and Senior Tutor	Yes	Chair and Meeting Chair
Ms Anna Rathmell	Associate Director Learning and Development, Pharmaceuticals	Yes	

Also in Attendance:

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