Health Research Authority

South Central - Oxford C Research Ethics Committee

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

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.

21 April 2022

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:	**SA004**
Amendment date:	**12 April 2022**
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:

Document	*Version*	*Date*
Completed Amendment Tool [SA004 Amendment Tool]	1.6	12 April 2022
Covering letter on headed paper [Cover Letter - Substantial Amendment 4]	1.0	12 April 2022
Letters of invitation to participant [EXAKT Enrolment Covering Letter]	1.0	12 April 2022
Letters of invitation to participant [UK-ROX and EXAKT Enrolment Covering Letter - Clean]	1.0	12 April 2022
Letters of invitation to participant [UK-ROX and EXAKT Enrolment Covering Letter - Tracked Changes]	1.0	12 April 2022
Other [EXAKT Nominated Consultee Information Sheet]	1.0	12 April 2022
Other [EXAKT Nominated Consultee Opinion Form]	1.0	12 April 2022
Other [EXAKT Personal Consultee Information Sheet]	1.0	12 April 2022
Other [EXAKT Personal Consultee Opinion Form]	1.0	12 April 2022
Other [EXAKT Postal Consent Form]	1.0	12 April 2022
Other [EXAKT Telephone Consent Form]	1.0	12 April 2022
Other [EXAKT Telephone Personal Consultee Opinion Form]	1.0	12 April 2022
Other [Schedule 6 - Variation of CTSA (mNCA)]	1.0	12 April 2022
Other [UK-ROX and EXAKT Nominated Consultee Information Sheet - Clean]	1.0	12 April 2022
Other [UK-ROX and EXAKT Nominated Consultee Information Sheet - Tracked Changes]	1.0	12 April 2022
Other [UK-ROX and EXAKT Nominated Consultee Opinion Form - Clean]	1.0	12 April 2022
Other [UK-ROX and EXAKT Nominated Consultee Opinion Form - Tracked Changes]	1.0	12 April 2022
Other [UK-ROX and EXAKT Personal Consultee Information Sheet - Clean]	1.0	12 April 2022
Other [UK-ROX and EXAKT Personal Consultee Information Sheet - Tracked Changes]	1.0	12 April 2022
Other [UK-ROX and EXAKT Personal Consultee Opinion Form - Clean]	1.0	12 April 2022
Other [UK-ROX and EXAKT Personal Consultee Opinion Form - Tracked Changes]	1.0	12 April 2022
Other [UK-ROX and EXAKT Postal Consent Form - Clean]	1.0	12 April 2022
Other [UK-ROX and EXAKT Postal Consent Form - Tracked Changes]	1.0	12 April 2022
Other [UK-ROX and EXAKT Telephone Consent Form - Clean]	1.0	12 April 2022
Other [UK-ROX and EXAKT Telephone Consent Form - Tracked Changes]	1.0	12 April 2022
Other [UK-ROX and EXAKT Telephone Personal Consultee Opinion Form - Clean]	1.0	12 April 2022
Other [UK-ROX and EXAKT Telephone Personal Consultee Opinion Form - Tracked Changes]	1.0	12 April 2022
Participant consent form [EXAKT Consent Form]	1.0	12 April 2022
Participant consent form [UK-ROX and EXAKT Consent Form - Clean]	1.0	12 April 2022
Participant consent form [UK-ROX and EXAKT Consent Form - Tracked Changes]	1.0	12 April 2022
Participant information sheet (PIS) [EXAKT Patient Information Sheet]	1.0	12 April 2022
Participant information sheet (PIS) [UK-ROX and EXAKT Patient Information Sheet - Clean]	1.0	12 April 2022
Participant information sheet (PIS) [UK-ROX and EXAKT Patient	1.0	12 April 2022

Information Sheet - Tracked Changes]		
Research protocol or project proposal [UK-ROX Trial Protocol - Clean]	1.5	12 April 2022
Research protocol or project proposal [UK-ROX Trial Protocol - Tracked Changes]	1.5	12 April 2022
Research protocol or project proposal [Protocol Addendum - EXAKT Sub-Study]	1.0	12 April 2022

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

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:	*Tasnin Shahid, Intensive Care National Audit & Research Centre (ICNARC)*

South Central - Oxford C Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 21 April 2022

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Lee Potiphar	Senior Lecturer in Adult Nursing and Senior Tutor	Yes	Chair
Dr Pamela Ross	GP Principal	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Simon Fisher	Approvals Administrator