South Central - Oxford C Research Ethics Committee
Health Research Authority (Bristol)
Ground Floor, Temple Quay House, 2 The Square
BS1 6PN

Telephone: 0207 104 8241

Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

17 February 2021_Revised 24 February 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**
IRAS project ID:	**288506**

Thank you for your letter of 17 February 2021. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 08 December 2020.

Documents Received

The documents received were as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Ethics re-submission letter]		21 December 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors		16 February 2021

only) [UK-ROX Insurance Confirmation]		
IRAS Checklist XML [Checklist_21122020]		21 December 2020
Other [Personal Consultee Information Sheet]	1.1	14 December 2020
Other [Nominated Consultee Information Sheet]	1.1	14 December 2020
Other [Patient Follow-up Letter]	1.1	14 December 2020
Other [Ethics Response to Queries Letter]		17 February 2021
Participant consent form [Telephone Personal Consultee Opinion Form (Tracked Changes)]	1.1	14 December 2020
Participant consent form [Telephone Personal Consultee Opinion Form]	1.1	14 December 2020
Participant consent form [Consent Form (Tracked Changes)]	1.1	14 December 2020
Participant consent form [Consent Form]	1.1	14 December 2020
Participant consent form [Nominated Consultee Opinion Form (Tracked Changes)]	1.1	14 December 2020
Participant consent form [Nominated Consultee Opinion Form]	1.1	14 December 2020
Participant consent form [Personal Consultee Opinion Form (Tracked Changes)]	1.1	14 December 2020
Participant consent form [Personal Consultee Opinion Form]	1.1	14 December 2020
Participant consent form [Postal Consent Form (Tracked Changes)]	1.1	14 December 2020
Participant consent form [Postal Consent Form]	1.1	14 December 2020
Participant consent form [Telephone Consent Form (Tracked Changes)]	1.1	14 December 2020
Participant consent form [Telephone Consent Form]	1.1	14 December 2020
Participant information sheet (PIS) [Patient Information Sheet]	1.1	14 December 2020
Research protocol or project proposal [UK-ROX Trial Protocol]	1.1	14 December 2020

Approved Documents

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

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Relatives room poster]	1.0	20 October 2020
Covering letter on headed paper [Ethics re-submission letter]		21 December 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance certificate]		14 August 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UK-ROX Insurance Confirmation]		16 February 2021
IRAS Application Form [IRAS_Form_29102020]		29 October 2020
IRAS Checklist XML [Checklist_21122020]		21 December 2020
Letter from funder [Funder letter]		07 July 2020
Letter from sponsor [Sponsor letter]		20 August 2020
Letters of invitation to participant [Enrolment Covering Letter]	1.0	20 October 2020
Non-validated questionnaire [Health Services Questionnaire]	1.0	20 October 2020
Other [Information Leaflet]	1.0	20 October 2020
Other [Patient Newsletter]	1.0	20 October 2020

Other [Personal Consultee Information Sheet]	1.1	14 December 2020
Other [Nominated Consultee Information Sheet]	1.1	14 December 2020
Other [Patient Follow-up Letter]	1.1	14 December 2020
Other [Ethics Response to Queries Letter]		17 February 2021
Participant consent form [Consent Form (Tracked Changes)]	1.1	14 December 2020
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Participant information sheet (PIS) [Patient Information Sheet]	1.1	14 December 2020
Referee's report or other scientific critique report [Response to board comments]		22 May 2020
Research protocol or project proposal [UK-ROX Trial Protocol]	1.1	14 December 2020
Summary CV for Chief Investigator (CI) [Professor Daniel Martin CV]		15 September 2020
Validated questionnaire [EQ-5D-5L Questionnaire]	1.0	20 October 2020

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.

IRAS Project ID: 288506 **Please quote this number on all correspondence**

Yours sincerely

Charlotte Ferris
Approvals Officer

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

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