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19 February 2021 *(re-issued 02/03/2021)*

Dear Professor Martin

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Evaluating the clinical and cost-effectiveness of a conservative approach to oxygen therapy for invasively ventilated adults in intensive care.**
IRAS project ID:	**288506**
Protocol number:	**01/10/20**
REC reference:	**20/SC/0423**
Sponsor	**Intensive Care National Audit & Research Centre (ICNARC)**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **288506**. Please quote this on all correspondence.

Yours sincerely,

Maeve Groot Bluemink
Approvals Manager

Email: approvals@hra.nhs.uk

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

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Contract/Study Agreement template [Clinical Trial Site Agreement]	1.0	20 October 2020
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
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
Organisation Information Document [Organisational Information Document]		
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 [Postal Consent Form]	1.1	14 December 2020
Participant consent form [Telephone Consent Form]	1.1	14 December 2020
Participant consent form [Telephone Personal Consultee Opinion Form]	1.1	14 December 2020
Participant consent form [Consent Form]	1.1	14 December 2020
Participant consent form [Nominated Consultee Opinion Form]	1.1	14 December 2020
Participant consent form [Personal Consultee Opinion Form]	1.1	14 December 2020
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
Schedule of Events or SoECAT [SoECAT]		02 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

IRAS project ID	288506

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
Research Site: All participating organisations will undertake the same activities, as detailed in the protocol and supporting documents.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	An Organisation Information Document has been submitted and the sponsor is intending to use a separate site agreement. The agreement is unmodified.	External funding has been secured from National Institute for Health Research (NIHR) - Heath Technology Assessment (HTA) Programme. An AcoRD Specialist authorised SoECAT has been submitted.	Principal Investigators (PIs) are expected for this type of study.	Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research application would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including

					appropriate barred list checks, and occupational health clearance. For research team members only administering questionnaires or surveys, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
• The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio. • The applicant has provided a list of sites in [Appendix 1] of the Cover Letter dated 21/12/2020. These sites are included in the Approval.