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South Central – Oxford C Research Ethics Committee
Health Research Authority
Ground Floor, Temple Quay House
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Bristol BS1 6PN

12 April 2022

Dear Research Ethics Committee,

Study title:	**Evaluating the clinical and cost-effectiveness of a conservative approach to oxygen therapy for invasively ventilated adults in intensive care (UK-ROX).**
REC reference:	**20/SC/0423**
Protocol number:	**01/10/20**
IRAS project ID:	**288506**
Amendment number:	**SA004**
Amendment date:	**12 April 2022**

We would be grateful if you would consider substantial amendment 4 dated 12 April 2022 which relates to the addition of the EXAKT *(**E**xploring pulse o**X**imeter **A**ccuracy across s**K**in **T**ones)* sub-study (NIHR152078) to the UK-ROX trial.

The rationale for adding this sub-study to UK-ROX is as follows:

Pulse oximeters are used in virtually every medical field and provide a non-invasive way of measuring blood oxygen levels. Recently, their accuracy has been brought into question and published retrospective data shows this inaccuracy may be related to patient ethnicity. It is thought that the inaccuracy is greatest in patients with darker skin tones. This potential healthcare inequality was identified by the Department of Health to be a research priority and urgent funds were made available through the National Institute for Health Research to conduct a prospective study that evaluates the accuracy of pulse oximeters in patients with different skin tones. Our research group was awarded this funding to add a sub-study to our already running UK-ROX trial that is evaluating conservative oxygen therapy in mechanically ventilated critically ill patients. By using the framework of the UK-ROX trial for the EXAKT sub-study we hope to be able to provide rapid results to the NHS that will answer the question of whether darker skin tone affects the accuracy of pulse oximeters.

Please let us know if any further information or clarification is required.

Many thanks in advance for considering this amendment.

Yours sincerely

Professor Daniel Martin OBE & Mr Paul Mouncey
Chief Investigators, UK-ROX Trial

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SA004 Amendment Tool
UK-ROX Trial Protocol v1.5, 12 April 2022 (tracked and clean versions)
Protocol Addendum – EXAKT Sub-Study v1.0, 12 April 2022
UK-ROX and EXAKT Patient Information Sheet v1.0, 12 April 2022 (tracked and clean versions)
UK-ROX and EXAKT Personal Consultee Information Sheet v1.0, 12 April 2022 (tracked and clean versions)
UK-ROX and EXAKT Nominated Consultee Information Sheet v1.0, 12 April 2022 (tracked and clean versions)
UK-ROX and EXAKT Consent Form v1.0, 12 April 2022 (tracked and clean versions)
UK-ROX and EXAKT Telephone Consent Form v1.0, 12 April 2022 (tracked and clean versions)
UK-ROX and EXAKT Postal Consent Form v1.0, 12 April 2022 (tracked and clean versions)
UK-ROX and EXAKT Nominated Consultee Opinion Form v1.0, 12 April 2022 (tracked and clean versions)
UK-ROX and EXAKT Personal Consultee Opinion Form v1.0, 12 April 2022 (tracked and clean versions)
UK-ROX and EXAKT Enrolment Covering Letter v1.0, 2022 (tracked and clean versions)
EXAKT Patient Information Sheet v1.0, 12 April 2022
EXAKT Personal Consultee Information Sheet v1.0, 12 April 2022
EXAKT Nominated Consultee Information Sheet v1.0, 12 April 2022
EXAKT Consent Form v1.0, 12 April 2022
EXAKT Telephone Consent Form v1.0, 12 April 2022
EXAKT Postal Consent Form v1.0, 12 April 2022
EXAKT Nominated Consultee Opinion Form v1.0, 12 April 2022
EXAKT Personal Consultee Opinion Form v1.0, 12 April 2022
EXAKT Enrolment Covering Letter v1.0, 12 April 2022
Schedule 6 – Variation of CTSA (mNCA) v1.0, 12 April 2022