

## SCHEDULE 6

### VARIATION TO mNCA FORM

**Project Title:** Evaluating the clinical and cost-effectiveness of a conservative approach to oxygen therapy for invasively ventilated adults in intensive care (UK-ROX)

**Funding Application Reference:** NIHR130508

**IRAS ID:** 288506

Variation to Agreement between:

Intensive Care National Audit & Research Centre (ICNARC)  
Napier House, 24 High Holborn, London, WC1V 6AZ,  
(referred to as “the Sponsor”)

AND

[Insert NAME AND ADDRESS OF PARTICIPATING SITE]  
(referred to as “the Participating Site”)

Variation No: 1

Date: [Insert date]

1. The Agreement is varied as follows:

- 1.1 (i) The variation is to add the Exploring Pulse OXimeter Accuracy Across Skin Tones (EXAKT) sub-study to the UK-ROX trial. The EXAKT study is a study within a trial to determine the effect of skin tone on the diagnostic accuracy of pulse oximeters. The sub-study was introduced as part of UK-ROX substantial amendment number 4 at selected sites.

#### Summary of study arrangements

Estimated number of EXAKT Participants to be recruited at the Site: [Insert number]

#### Supplies arrangements

- **Pulse oximeters**

The NHS COVID Oximetry @home scheme will provide pulse oximeters that require evaluation. Each site participating in the sub-study will be randomly allocated two brands of pulse oximeters from the COVID Oximetry @home list to evaluate.

- **CM-600d spectrophotometer**

**Study Title:** UK-ROX

**Reference:** IRAS – 288506, NIHR HTA - NIHR130508, ICNARC - 01/10/20

The spectrophotometer will be provided by Konica Minolta.

### **Financial arrangements**

|   | <b>Area of Cost</b>                 | <b>Payment (£ Sterling)</b> |
|---|-------------------------------------|-----------------------------|
| 1 | Per eligible EXAKT patient enrolled | £50.00                      |

**SIGNED:**

|                         |                      |
|-------------------------|----------------------|
| Sponsor Representative: | Site Representative: |
| Signature:              | Signature:           |
| Name:                   | Name:                |
| Position:               | Position:            |
| Date:                   | Date:                |