



## SECTION 2: BEFORE SURGERY



SUBJECT #

|\_|\_|\_|-|\_|\_|\_|\_|

SITE #

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| CO-MORBID DISEASE |  | YES                      | NO                       |
|-------------------|--|--------------------------|--------------------------|
| 1.                | Chronic respiratory disease  |                          |                          |
|                   | Chronic obstructive pulmonary disease (COPD)   | <input type="checkbox"/> | <input type="checkbox"/> |
|                   | Asthma   | <input type="checkbox"/> | <input type="checkbox"/> |
|                   | Interstitial lung disease or pulmonary fibrosis  | <input type="checkbox"/> | <input type="checkbox"/> |
|                   | Bronchiectasis   | <input type="checkbox"/> | <input type="checkbox"/> |
| 2.                | Ischaemic heart disease  | <input type="checkbox"/> | <input type="checkbox"/> |
| 3.                | Diabetes mellitus  | <input type="checkbox"/> | <input type="checkbox"/> |
| 4.                | Heart failure  | <input type="checkbox"/> | <input type="checkbox"/> |
| 5.                | Liver cirrhosis  | <input type="checkbox"/> | <input type="checkbox"/> |
| 6.                | Active cancer  | <input type="checkbox"/> | <input type="checkbox"/> |
|                   | If yes – is cancer the indication for surgery?   | <input type="checkbox"/> | <input type="checkbox"/> |
|                   | If yes - is the surgery intended to be: <input type="checkbox"/> curative or <input type="checkbox"/> palliative |                          |                          |
| 7.                | Previous stroke or transient ischaemic attack (TIA)  | <input type="checkbox"/> | <input type="checkbox"/> |
| 8.                | Current smoker (within the last 14 days)?  | <input type="checkbox"/> | <input type="checkbox"/> |
| 9.                | Primary respiratory infection within the previous month (including acute pulmonary tuberculosis)?                | <input type="checkbox"/> | <input type="checkbox"/> |
| 10.               | Diagnosis of Human Immunodeficiency Virus (HIV) infection? <i>NB. If not tested please tick 'no'.</i>            | <input type="checkbox"/> | <input type="checkbox"/> |

| OTHER DETAILS   |  |                                    |  |
|---|--|------------------------------------|--|
| National ID number  | _ _ _ _ _ _ _ _ _ _ _ _ _ _                      |                                    |  |
| ASA (American Society of Anesthesiologists) physical status class |  |                                    |  |
| Class I <input type="checkbox"/>                                  | Class II <input type="checkbox"/>                | Class III <input type="checkbox"/> | Class IV <input type="checkbox"/> Class V <input type="checkbox"/> |
| Physical measurements   |  |                                    |  |
| Height (cm):  | _ _ _  | Weight (kg):                       | _ _ _  |
| Resting oxygen saturation (SpO <sub>2</sub> ):                    |  | _ _ _  %                           |  |
| Laboratory values (within 4 weeks before surgery)                 |  |                                    | Tick if NOT measured   |
| Haemoglobin measurement   | _ _ _  g/dL                                      | <input type="checkbox"/>           |  |
| Creatinine measurement  | _ _ _  μmol/L                                    | <input type="checkbox"/>           |  |
| Ethnicity (for eGFR)  | Black or Afro-Caribbean <input type="checkbox"/> | Other <input type="checkbox"/>     |  |

**SECTION 3: DURING SURGERY**

SUBJECT #

|\_|\_|\_|-|\_|\_|\_|\_|

SITE #

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**START OF SURGERY**DATE: |\_|\_|\_|/|\_|\_|\_|\_|\_|/|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|  
(DD/MMM/YYYY)TIME: |\_|\_|\_| : |\_|\_|\_|  
(HR : MINS)

| <b>SURGICAL PROCEDURE PERFORMED (single most appropriate)</b>                        | <b>Tick one</b>   |                                |
|--|---|--------------------------------|
| Resection of colon, rectum or small bowel  | <input type="checkbox"/>  |                                |
| Resection of liver, pancreas or gall bladder   | <input type="checkbox"/>  |                                |
| Resection of stomach (non-obesity surgery)   | <input type="checkbox"/>  |                                |
| Resection of oesophagus (non-obesity)  | <input type="checkbox"/>  |                                |
| Obesity surgery  | <input type="checkbox"/>  |                                |
| Vascular procedure   | <input type="checkbox"/>  |                                |
| Other intra-peritoneal surgery   | <input type="checkbox"/>  |                                |
| <b>SURGICAL TECHNIQUE</b>  | <b>YES</b>  | <b>NO</b>                      |
| Open surgical technique used during surgery  | <input type="checkbox"/>  | <input type="checkbox"/>       |
| <b>ANAESTHETIC TECHNIQUE</b>   |   |                                |
| General Anaesthesia  | <input type="checkbox"/>  | <input type="checkbox"/>       |
| Epidural anaesthesia   | <input type="checkbox"/>  | <input type="checkbox"/>       |
| Spinal anaesthesia   | <input type="checkbox"/>  | <input type="checkbox"/>       |
| Did the patient have an endotracheal tube inserted?                                  | <input type="checkbox"/>  | <input type="checkbox"/>       |
| If YES, was the patient extubated before leaving the operating room?                 | <input type="checkbox"/>  | <input type="checkbox"/>       |
| <b>MECHANICAL VENTILATION DURING SURGERY</b>   |   |                                |
| Did the patient receive a recruitment manoeuvre during surgery?                      | <input type="checkbox"/>  | <input type="checkbox"/>       |
| Did the patient receive mechanical ventilation during surgery?                       | <input type="checkbox"/>  | <input type="checkbox"/>       |
| If YES, please answer the following:   |   |                                |
| Maximum positive end-expiratory pressure (PEEP)                                      | _ _ _  cmH <sub>2</sub> O   |                                |
| Maximum set tidal volume (Vt)  | _ _ _ _  ml   |                                |
| Maximum respiratory rate   | _ _ _  min <sup>-1</sup>  |                                |
| Maximum FiO <sub>2</sub> (excluding pre-oxygenation during induction of anaesthesia) | _ _ _  %  |                                |
| <b>INTRAVENOUS FLUIDS DURING SURGERY</b>   |   |                                |
| Total volume of intravenous fluid administered excluding blood products              | _ _ _ _ _  mL   |                                |
| Total volume of blood products administered  | _ _ _ _ _  mL   |                                |
| <b>Date and time of the end of surgery</b>   | _ _ _ / _ _ _ _ _ / _ _ _ _ _ _ _ _ _ _ _ _ _ _ <br>(DD/MMM/YYYY) | _ _ _  :  _ _ _ <br>(HR: MINS) |

**SECTION 4: TRIAL INTERVENTION PERIOD**

|                  |                 |               |                           |
|------------------|-----------------|---------------|---------------------------|
| <b>SUBJECT #</b> | _ _ _ - _ _ _ _ | <b>SITE #</b> | _ _ _ _ _ _ _ _ _ _ _ _ _ |
|------------------|-----------------|---------------|---------------------------|

| <b>CPAP AFTER SURGERY</b>  |   | <b>YES</b>                | <b>NO</b>                |
|--|---|---------------------------|--------------------------|
| Did the patient receive Continuous Positive Airway Pressure (CPAP) started within twelve hours after the end of surgery? |   | <input type="checkbox"/>  | <input type="checkbox"/> |
| If YES, please answer the following questions. If NO, please skip to next section.                                       |   |                           |                          |
| Date and time patient started CPAP   | _ _ / _ _ _ _ / _ _ _ _ <br>(DD/MMM/YYYY) | _ _ : _ _ <br>(HR:MINS)   |                          |
| Total duration of CPAP within twelve hours of the end of surgery   |   | _ _ _ <br>(MINS)          |                          |
| Maximum airway pressure received during this period  |   | _ _ _  cmH <sub>2</sub> O |                          |
| Primary method of CPAP delivery (single most appropriate)  |   |                           |                          |
| Face mask  |   | <input type="checkbox"/>  |                          |
| Helmet device  |   | <input type="checkbox"/>  |                          |
| Nasal mask   |   | <input type="checkbox"/>  |                          |
|  |   | <b>YES</b>                | <b>NO</b>                |
| Were extra research staff present to help deliver CPAP?  |   | <input type="checkbox"/>  | <input type="checkbox"/> |
| Did the staff administering CPAP use equipment to monitor airway pressures?  |   | <input type="checkbox"/>  | <input type="checkbox"/> |
| Did the staff administering CPAP use equipment to monitor the FiO <sub>2</sub> ?   |   | <input type="checkbox"/>  | <input type="checkbox"/> |
| Did the patient have a nasogastric tube <i>in situ</i> during CPAP?  |   | <input type="checkbox"/>  | <input type="checkbox"/> |

| <b>RESPIRATORY SUPPORT AFTER SURGERY</b>  |  | <b>YES</b>               | <b>NO</b>                |
|---|--|--------------------------|--------------------------|
| Did the patient receive any of the following within four hours of the end of surgery? |  |                          |                          |
| Invasive mechanical ventilation   |  | <input type="checkbox"/> | <input type="checkbox"/> |
| Non-invasive mechanical ventilation   |  | <input type="checkbox"/> | <input type="checkbox"/> |
| High flow nasal oxygen therapy  |  | <input type="checkbox"/> | <input type="checkbox"/> |

| <b>LEVEL OF CARE ON THE FIRST NIGHT AFTER SURGERY</b> | <b>Tick one</b>          |
|---|--------------------------|
| Critical care unit level 3                            | <input type="checkbox"/> |
| Critical care unit level 2                            | <input type="checkbox"/> |
| Post-anaesthesia care unit                            | <input type="checkbox"/> |
| Surgical ward   | <input type="checkbox"/> |





**SECTION 5: 30-DAY FOLLOW-UP**

|                  |                 |               |                                       |
|------------------|-----------------|---------------|---------------------------------------|
| <b>SUBJECT #</b> | _ _ _ - _ _ _ _ | <b>SITE #</b> | _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ |
|------------------|-----------------|---------------|---------------------------------------|

| <b>Patients admitted to a critical care unit</b>  | <b>YES</b>               | <b>NO</b>                |
|---|--------------------------|--------------------------|
| Was the participant admitted to a critical care unit? <i>NB. If 'no', move to the next section.</i> | <input type="checkbox"/> | <input type="checkbox"/> |
| Was the critical care admission to treat a complication?  | <input type="checkbox"/> | <input type="checkbox"/> |
| Was a planned critical care admission prolonged by a postoperative complication?                    | <input type="checkbox"/> | <input type="checkbox"/> |
| What was the total duration of the level 2 critical care stay within 30 days of randomisation?      | _ _  days                |                          |
| What was the total duration of the level 3 critical care stay within 30 days of randomisation?      | _ _  days                |                          |
| <b>Details of the hospital stay</b>   | <b>YES</b>               | <b>NO</b>                |
| Duration of primary hospital admission (from randomisation)   | _ _  days                |                          |
| Re-admission to hospital within 30 days of randomisation  | <input type="checkbox"/> | <input type="checkbox"/> |

| <b>Investigator self-assessment of blinding</b> |                          |
|---|--------------------------|
| I was suitably blinded                          | <input type="checkbox"/> |
| I may have known the study group allocation     | <input type="checkbox"/> |
| I definitely knew the study group allocation    | <input type="checkbox"/> |

**The self-assessment of blinding should be completed by the investigator that collects the 30-day follow up data. This assessment only applies to data collection at this time point**





**SUPPLEMENTARY FORM: WITHDRAWAL****SUBJECT #**

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**SITE #**

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**ONLY COMPLETE THIS FORM IF THE PARTICIPANT PREMATURELY STOPPED THEIR PARTICIPATION IN THE TRIAL OR IF THEY COULD NOT BE CONTACTED**

|  |   |
|--|---|
| <b>Date the patient prematurely discontinued study participation:</b>    | _ _ _ / _ _ _ _ _ / _ _ _ _ _ <br>(DD-MMM-YYYY)   |
| <b>What was the primary reason for the discontinuation of the study?</b> | <input type="checkbox"/> Inclusion/Exclusion criteria not fulfilled<br><input type="checkbox"/> Surgical procedure abandoned<br><input type="checkbox"/> Adverse event related<br><input type="checkbox"/> Patient initiated<br><input type="checkbox"/> Other, specify:<br>_____ |
| <b>In the case of patient withdrawal, please check:</b>                  | <input type="checkbox"/> The participant agrees that any data collected up to the date of withdrawal can still be used.<br><input type="checkbox"/> The patient would like their data removed from the database.  |

**SUPPLEMENTARY FORM: ADVERSE EVENT DURING CPAP**



|                  |                 |               |                           |
|------------------|-----------------|---------------|---------------------------|
| <b>SUBJECT #</b> | _ _ _ - _ _ _ _ | <b>SITE #</b> | _ _ _ _ _ _ _ _ _ _ _ _ _ |
|------------------|-----------------|---------------|---------------------------|

**ONLY COMPLETE THIS FORM IF THE PATIENT EXPERIENCED AN ADVERSE EVENT DURING CPAP**

*In the case of multiple adverse events, please complete a separate form for each one.*

| ADVERSE EVENT RELATED TO CPAP FORM – PAGE 1  |   | NO                       | YES                      |
|--|---|--------------------------|--------------------------|
| Did the patient experience an adverse event related to Continuous Positive Airway Pressure (CPAP) that was delivered as part of the PRISM trial? |   | <input type="checkbox"/> | <input type="checkbox"/> |
| If YES, please answer the following questions.   |   |                          |                          |
| Date and time of onset of adverse event  | _ _ / _ _ _ _ / _ _ _ _ <br>(DD/MMM/YYYY) | _ _ : _ _ <br>(HR:MIN)   |                          |
| Adverse Event  | NO  | YES                      |                          |
| Interface intolerance due to excessive air leak  | <input type="checkbox"/>                  | <input type="checkbox"/> |                          |
| Pain   | <input type="checkbox"/>                  | <input type="checkbox"/> |                          |
| Cutaneous pressure area  | <input type="checkbox"/>                  | <input type="checkbox"/> |                          |
| Claustrophobia   | <input type="checkbox"/>                  | <input type="checkbox"/> |                          |
| Oronasal dryness   | <input type="checkbox"/>                  | <input type="checkbox"/> |                          |
| Hypercapnia  | <input type="checkbox"/>                  | <input type="checkbox"/> |                          |
| Haemodynamic instability   | <input type="checkbox"/>                  | <input type="checkbox"/> |                          |
| Vomiting   | <input type="checkbox"/>                  | <input type="checkbox"/> |                          |
| Aspiration of gastric contents   | <input type="checkbox"/>                  | <input type="checkbox"/> |                          |
| Other:   | <input type="checkbox"/>                  | <input type="checkbox"/> |                          |
| Response to adverse event  | Tick one                                  |                          |                          |
| CPAP was <i>unchanged</i>  | <input type="checkbox"/>                  |                          |                          |
| CPAP was <i>modified</i>   | <input type="checkbox"/>                  |                          |                          |
| CPAP was <i>stopped</i>  | <input type="checkbox"/>                  |                          |                          |
| Outcome of adverse event   | NO  | YES                      |                          |
| If YES to any option below, please notify the PRISM trial coordinating centre within 24 hours by email.  |   |                          |                          |
| Death  | <input type="checkbox"/>                  | <input type="checkbox"/> |                          |
| Life-threatening complication  | <input type="checkbox"/>                  | <input type="checkbox"/> |                          |
| Prolonged hospital stay  | <input type="checkbox"/>                  | <input type="checkbox"/> |                          |
| Significant disability or incapacity   | <input type="checkbox"/>                  | <input type="checkbox"/> |                          |

**SUPPLEMENTARY FORM: ADVERSE EVENT DURING CPAP****SUBJECT #**

|\_|\_|\_|\_|-|\_|\_|\_|\_|

**SITE #**

|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|

**ADVERSE EVENT RELATED TO CPAP FORM – PAGE 2**

Please describe the adverse event, including any treatment or medication required.

Name and signature:

Date:



