



**SECTION 2: BEFORE SURGERY**


<b>SUBJECT #</b>	_ _ _ - _ _ _ _	<b>SITE #</b>	_ _ _ _ _ _ _ _ _ _ _ _ _ _
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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			
Codice fiscale	_ _ _ _ _ _ _ - _ _ - _ - _ _ - _ - _ _ _ _ _		
Postal code	_ _ _ _		
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	_ _ _  mg/dL		<input type="checkbox"/>
Ethnicity (for eGFR)	Black or Afro-Caribbean	<input type="checkbox"/>	Other <input type="checkbox"/>

**SECTION 3: DURING SURGERY****SUBJECT #**

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

**SITE #**

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

**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>	_ _ _ / _ _ _ _ _ / _ _ _ _ _ _ _ _ _ _ _ _ _ _  (DD/MMM/YYYY)	_ _ _  :  _ _ _ _ _  (HR:MINS)

**SECTION 4: TRIAL INTERVENTION PERIOD**

<b>SUBJECT #</b>	_ _ _ - _ _ _ _	<b>SITE #</b>	_ _ _ _ _ _ _ _ _ _ _ _ _
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<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	_ _ _ / _ _ _ _ / _ _ _ _ _  (DD/MMM/YYYY)	_ _  : _ _   (HR:MINS)	
Total duration of CPAP within twelve hours of the end of surgery		_ _ _  (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>	_ _ _ _ _ _ _ _ _ _ _ _ _
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<b>Date of follow-up</b>	_ _ / _ _ _ _ / _ _ _ _ _ _ _ _  (DD-MMM-YYYY)
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All of the outcomes in section 5 refer to the time period within 30 days of randomisation			
Primary outcome	YES	NO	If yes, date of event
Pneumonia	<input type="checkbox"/>	<input type="checkbox"/>	_ _ / _ _ _ _ / _ _ _ _ _ _ _ _  (DD-MMM-YYYY)
Endotracheal re-intubation	<input type="checkbox"/>	<input type="checkbox"/>	_ _ / _ _ _ _ / _ _ _ _ _ _ _ _  (DD-MMM-YYYY)
Death	<input type="checkbox"/> Alive	<input type="checkbox"/> Dead	Date of death:  _ _ / _ _ _ _ / _ _ _ _ _ _ _ _  (DD-MMM-YYYY)

<b>Respiratory complications</b>	<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>	<b>V</b>	<b>NONE</b>
Pneumonia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pleural effusion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pneumothorax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bronchospasm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Aspiration pneumonitis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Acute Respiratory Distress Syndrome (ARDS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Infective complications</b>	<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>	<b>V</b>	<b>NONE</b>
Surgical site infection (superficial)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Surgical site infection (deep)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Surgical site infection (organ space)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Urinary tract infection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Infection, source uncertain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Laboratory confirmed blood stream infection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please refer to the protocol appendix for specific definitions of complications. Please grade complications using the Clavien-Dindo scale as follows:

- I. Any deviation from the normal postoperative course without the need for pharmacological, surgical, endoscopic or radiological intervention. Anti-emetics, anti-pyretics, diuretics, electrolytes or physiotherapy are not considered a deviation from the normal postoperative course.
- II. Requires pharmacological treatment with drugs (including blood transfusion or total parenteral nutrition) other than those excluded from grade I.
- III. Requires surgical, endoscopic or radiological intervention.
- IV. Life-threatening complication (including CNS complication, but excluding transient ischaemic attack) requiring critical care admission
- V. Death

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


<b>SUBJECT #</b>	_ _ _ - _ _ _ _	<b>SITE #</b>	_ _ _ _ _ _ _ _ _ _ _ _ _
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<b>Cardiac complications</b>	<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>	<b>V</b>	<b>NONE</b>
Myocardial infarction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Arrhythmia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cardiogenic pulmonary oedema	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cardiac arrest with successful resuscitation				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<b>Other complications</b>	<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>	<b>V</b>	<b>NONE</b>
Acute kidney injury	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pulmonary embolism	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stroke	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Acute psychosis or delirium	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bowel infarction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anastomotic leak	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Perforation of viscus (e.g. bowel, gall bladder etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Postoperative haemorrhage						
Gastro-intestinal bleed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other postoperative haemorrhage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Any other complication, <i>please give details here:</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<b>Additional treatments</b>	<b>YES</b>	<b>NO</b>
Blood transfusion	<input type="checkbox"/>	<input type="checkbox"/>
Parenteral (intra-venous) nutrition	<input type="checkbox"/>	<input type="checkbox"/>
Endoscopy or interventional radiology procedure	<input type="checkbox"/>	<input type="checkbox"/>
Repeat surgery	<input type="checkbox"/>	<input type="checkbox"/>
If YES, please indicate the reason for repeat surgery		
Infection	<input type="checkbox"/>	<input type="checkbox"/>
Bleeding	<input type="checkbox"/>	<input type="checkbox"/>
Anastomotic leak	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>
Invasive mechanical ventilation after leaving the operating room	<input type="checkbox"/>	<input type="checkbox"/>
If YES, what was the total duration of invasive mechanical ventilation?	_ _ _  hours	
Non-invasive mechanical ventilation after leaving the operating room	<input type="checkbox"/>	<input type="checkbox"/>
If YES, what was the total duration of non-invasive mechanical ventilation?	_ _ _  hours	

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

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

**SECTION 6: ONE-YEAR FOLLOW-UP**

<b>SUBJECT #</b>	_ _ _ - _ _ _ _	<b>SITE #</b>	_ _ _ _ _ _ _ _ _ _ _ _ _
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<b>Date of follow-up</b>	_ _ / _ _ _ _ / _ _ _ _  (DD-MMM-YYYY)
<b>Patient status on date of follow-up</b>	<input type="checkbox"/> Alive <input type="checkbox"/> Dead: date of death:  _ _ / _ _ _ _ / _ _ _ _  (DD-MMM-YYYY)



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

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

**SITE #**

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

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

**Date the patient prematurely discontinued study participation:**

|\_|\_|\_|/|\_|\_|\_|\_|/|\_|\_|\_|\_|\_|  
(DD-MMM-YYYY)

**What was the primary reason for the discontinuation of the study?**

- Inclusion/Exclusion criteria not fulfilled
- Surgical procedure abandoned
- Adverse event related
- Patient initiated
- Other, specify:  
\_\_\_\_\_

**In the case of patient withdrawal, please check:**

- The participant agrees that any data collected up to the date of withdrawal can still be used.
- The patient would like their data removed from the database.

**SUPPLEMENTARY FORM: ADVERSE EVENT DURING CPAP**



<b>SUBJECT #</b>	_ _ _ - _ _ _ _	<b>SITE #</b>	_ _ _ _ _ _ _ _ _ _ _ _ _ _
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**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	_ _ / _ _ _ _ / _ _ _ _  (DD/MMM/YYYY)	_ _ : _ _  (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 #**

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**SITE #**

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

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

Name and signature:

Date:



