SECTION 1: INCLUSION, EXCLUSION & RANDOMISATION INFORMATION							
SUBJECT # _ _ - _ SITE #	<i>f</i> _ _ _						
DEMOGRAPHIC INFORMATION							
Given name	Family name	_ _ _	_				
Date of birth _ / _ _ / _ _	Gender	Female		Male □			
Consent date _ / _ / _ _	Date of surgery	_/ _	_ <u> </u> <u> </u> DD/MMM/YYYY)				
NO USE OF STATE OF ST			V/50	NO.			
INCLUSION & EXCLUSION CRITERIA			YES	NO			
Age ≥ 50 years							
Planned elective major intra-peritoneal surgery usi	ng an open surgical	technique					
Inability or refusal to provide informed consent							
Anticipated requirement for invasive or non-invasive least four hours after surgery as part of routine car							
Known or suspected pregnancy or planned obstetr							
Previous enrolment in the PRISM trial							
Current participation in another clinical trial of a tre mechanism or primary outcome measure							
Clinician refusal (concern specific to surgical procedure)							
Clinician refusal (other)							
Contraindication to continuous positive airway pressure (CPAP)							
Planned level of care on the first night after sur	gery		Tick	one			
Critical care unit level 3							
Critical care unit level 2							
Post-anaesthesia care unit							
Surgical ward							
RANDOMISATION CRITERIA			Tick	one			
Planned surgical procedure (single most appro	priate)		_				
Resection of colon, rectum or small bowel							
Resection of liver, pancreas or gall bladder							
Resection of stomach (non-obesity surgery)							
Resection of oesophagus (non-obesity surgery)							
Obesity surgery							
Vascular procedure							
Other intra-peritoneal surgery							
Planned anaesthetic technique			YES	NO			
Planned use of epidural anaesthesia							

Randomisation should only take place once it is certain that surgery will take place

SEC	CTION 2	2: BEFORE SURGERY			
SUE	SJECT #	_ _ - - - - - - - - - - - - - - - - -	_		
CO-	MORBID	DISEASE		YES	NO
1.	Chronic	c respiratory disease			
	Chro	onic obstructive pulmonary disease (COPD)			
	Asth	nma			
	Inte	rstitial lung disease or pulmonary fibrosis			
	Bror	nchiectasis			
2.	Ischaen	mic heart disease			
3.	Diabete	es mellitus			
4.	Heart fa	ailure			
5.	Liver ci	rrhosis			
6.	Active of	cancer			
	If ye	es – is cancer the indication for surgery?			
		If yes - is the surgery intended to be: \Box curati	ve or □ pal	lliative	
7.	Previou	us stroke or transient ischaemic attack (TIA)			
8.	Current	t smoker (within the last 14 days)?			
9.	tubercu				
10.	Diagnos please	f not tested			
	ER DET				
	ce fiscale	e _ _ _ _ _ _ _ _ _	_ -		
	al code				
ASA	•	an Society of Anesthesiologists) physical status class	Class V 🗆		
Dhys	Class		Class V □		
	ht (cm):	asurements _ Weight (kg):	1 1	1 1	
ı ı c ıy	• •	sting oxygen saturation (SpO ₂):			
Labo		alues (within 4 weeks before surgery)	· · · ·	OT meas	sured

|_|_| g/dL

|__|_| mg/dL

Black or Afro-Carribean □

Haemoglobin measurement

Creatinine measurement

Ethnicity (for eGFR)

Other \square

SECTION 3: DURING SURGE	RY						
SUBJECT # _ _ - _ SITE # _ _ _							
START OF SURGERY	DA	ATE: <u> </u> / <u> </u> (DD	/ TIME: /MMM/YYYY)	_ : (HR:MINS)			
SURGICAL PROCEDURE PERFO	ORI	MED (single most	appropriate)	Tick	one		
Resection of colon, rectum or sma			,				
Resection of liver, pancreas or gal	ll bla	adder					
Resection of stomach (non-obesity	y su	rgery)					
Resection of oesophagus (non-ob	esit	y)					
Obesity surgery							
Vascular procedure							
Other intra-peritoneal surgery							
SURGICAL TECHNIQUE				YES	NO		
Open surgical technique used dur	ing	surgery					
ANAESTHETIC TECHNIQUE							
General Anaesthesia							
Epidural anaesthesia							
Spinal anaesthesia							
Did the patient have an endotrach	eal	tube inserted?					
If YES, was the patient extubate			perating room?				
MECHANICAL VENTILATION DU	JRII	NG SURGERY					
Did the patient receive a recruitme							
Did the patient receive mechanica			jery?				
If YES, please answer the follow				<u> </u>			
Maximum positive end-expiratory pressure (PEEP) _ cmH ₂ O					:mH ₂ O		
Maximum set tidal volume (Vt) _ ml					_ ml		
Maximum respiratory rate	Maximum respiratory rate _ min ⁻¹						
Maximum FiO ₂ (excluding	pre-	oxygenation during	induction of anaesthesia)		%		
INTRAVENOUS FLUIDS DURING	S SI	JRGERY					
Total volume of intravenous fluid a	adm	inistered excluding	blood products		_ _ mL		
Total volume of blood products administered _ _ _				_ _ mL			

Date and time of the end of surgery

SUBJECT#	- - -	SITE#				
CPAP AFTE				YES	NO	
Did the patier twelve hours						
	If YES, please answer th	ne following quest	ions. If NO, please skip to next se	ection.		
Date and time	e patient started CPAP		_ / _ _ / _ (DD/MMM/YYYY)	_ : (HR:M	_ IINS)	
Total duration	n of CPAP within twelve h	nours of the end o	of surgery	_ (MIN	<u> </u> S)	
Maximum air	way pressure received do	uring this period			cmH ₂ O	
Primary meth	od of CPAP delivery (sin	gle most appropri	iate)			
Face masl	k]	
Helmet device						
Nasal mask						
				YES	NO	
Were extra re	esearch staff present to h	elp deliver CPAP	?			
Did the staff administering CPAP use equipment to monitor airway pressures?						
Did the staff administering CPAP use equipment to monitor the FiO ₂ ?						
Did the patient have a nasogastric tube in situ during CPAP?						
RESPIRATO	RY SUPPORT AFTER S	URGERY		YES	NO	
Did the patier	nt receive any of the follo	wing within four h	ours of the end of surgery?	_		
Invasive m	nechanical ventilation					
Non-invas	ive mechanical ventilation	n				
High flow I	nasal oxygen therapy					
LEVEL OF CARE ON THE FIRST NIGHT AFTER SURGERY					one	
Critica	al care unit level 3]	
Critica	al care unit level 2]	
Post-a	anaesthesia care unit					
Surgical ward						

SECTION 4: TRIAL INTERVENTION PERIOD

SECTION 5: 30-DAY FOLLOW-UP							ı	
SUBJECT # _ -	_ _ -		<u> </u>			_		
		_						
Date of follow-up			L	_ / _ (DD	/ <u> </u> -MMM-YYYY)			
All of the outcome	es in sectio	n 5 refer to 1	the time n	eriod with	in 30 day	s of rand	lomisatio	on
Primary outcome	YES	NO			f yes, date			J 11
Pneumonia	П	П				 / _	_	
Tricumonia					(DD-MMN	/I-YYYY)		
Endotracheal re-intubation				.	/ (DD-MMN	/ _ /I-YYYY)	_ _	
Death	☐ Alive	□ Dead	Date of death: _ / _ / _ _					
Respiratory complications	s		ı	II	III	IV	V	NONE
Pneumonia								
Pleural effusion								
Pneumothorax								
Bronchospasm								
Aspiration pneumonitis								
Acute Respiratory Distress	Syndrome (ARDS)						
Infective complications			I	II	III	IV	V	NONE
Surgical site infection (supe	erficial)							
Surgical site infection (deep)							
Surgical site infection (orga	Surgical site infection (organ space)							
Urinary tract infection								
Infection, source uncertain								
Laboratory confirmed blood	stream infe	ction						
	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, diruetics, 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										
SUBJECT#	_ - - -	SITE#	SITE # _ _ _ _ _			_				
• "										Neve
Cardiac com	•		I		II	III		<u>V</u>	V	NONE
Myocardial int	farction						_			
Arrhythmia							-	<u> </u>		
	oulmonary oedema	tation						<u> </u>		
Cardiac arres	t with successful resuscit	lalion					L			
Other compl	lications		ı		l II	III	ľ	V	V	NONE
Acute kidney										
Pulmonary er										
Stroke										
Acute psycho	osis or delirium									
Bowel infarct	ion									
Anastomotic	leak									
Perforation of viscus (e.g. bowel, gall bladder etc)										
Postoperative	e haemorrhage								•	•
Gastro-inte	estinal bleed									
Other postoperative haemorrhage										
Any other complication, please give details here:										
									l	-1
Additional tr	reatments								YES	NO
Blood transfu	ısion									
Parenteral (ir	ntra-venous) nutrition									
Endoscopy or interventional radiology procedure										
Repeat surgery										
If YES,	please indicate the reas	on for repeat	surge	ry						
Infection										
Bleeding										
Anastomotic leak										
	Other									
Invasive med	chanical ventilation after l	eaving the op	eratin	g ro	om					
If YES,	what was the total durat	ion of invasive	e mec	hani	ical ventila	tion?				_ hours
Non-invasive mechanical ventilation after leaving the operating room										

If YES, what was the total duration of non-invasive mechanical ventilation?

|__|_| hours

SECTION 5	: 30-DAY FOLLOW-UI	P	
SUBJECT#	_ - - - -	SITE#	

YES	NO	
What was the total duration of the level 2 critical care stay within 30 days of randomisation?		
_ days		
VES	NO	
123	110	
_	days	
_ _		

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

I may have known the study group allocation

I definitely knew the study group allocation

SUBJECT#	_ - - -	SITE#			
Date of follo	w-up	_ / _ / _ _ (DD-MMM-YYYY)			
Patient statu	us on date of follow-up	☐ Alive ☐ De	ad: date of death: _ / _ / (DD-MMM-YYYY)		

SECTION 6: ONE-YEAR FOLLOW-UP

SUPPLEMETARY 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					
SUBJECT#	_ - - - -	SITE#	_ _		

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?			
If YES, please answer the following questions.			
Date and time of onset of adverse event _/ / _ _ / _ _ _	_ : (HR:M	_ INS)	
Adverse Event	NO	YES	
Interface intolerance due to excessive air leak			
Pain			
Cutaneous pressure area			
Claustrophobia			
Oronasal dryness			
Hypercapnia			
Haemodynamic instability			
Vomiting			
Aspiration of gastric contents			
Other:			
Response to adverse event	Tick	one	
CPAP was <i>unchanged</i>			
CPAP was <i>modified</i>			
CPAP was stopped			
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			
Life-threatening complication			
Prolonged hospital stay			
Significant disability or incapacity			

SUBJECT#	-	SITE#	_		
ADVERSE E	VENT RELATED TO CP	AP FORM - PAGE	2		
Please descr	ibe the adverse event, in	cluding any treatme	ent or me	edication required.	
					ļ
Name and sig	gnature:			Date:	

SUPPLEMENTARY FORM: ADVERSE EVENT DURING CPAP

SUPPLEMENTARY FORM: PROTOCOL DEVIATION				
SUBJECT#	_ - - - _	SITE#	_	

ONLY COMPLETE THIS FORM IF THERE IS A PROTOCOL DEVIATION

Participant in the intervention group did NOT receive CPAP				
NB. This includes instances where CPAP is started more than twelve hours after the end of surgery. If CPAP was administered, but for only a brief duration, please record this in the next section below.				
Please indicate the reason				
CPAP was not offered				
Participant remained intubated after surgery				
Inadequate staffing or process issues				
Participant or clinician refusal				
Participant was too unwell to receive CPAP				
Equipment failure				
Other (please state):				
CPAP administered for less than 4 hours duration				
NB. This includes instances where CPAP was administered, but only for a brief duration	on			
Please indicate the reason				
Participant or clinician refusal				
Inadequate staffing or process issues				
Participant too unwell to continue with CPAP				
Equipment failure				
Other (please state):				
CPAP administered with significant interruption	la a internaciona			
NB. Brief interruptions to adjust mask, or for oral/nursing care are considered part of the intervention and do not require a protocol deviation form to be completed				
Please indicate the reason	ı			
Participant or clinician refusal				
Inadequate staffing or process issues				
Participant too unwell to continue with CPAP				
Equipment failure				
Other (please state):				

SUPPLEMENTARY FORM: PROTOCOL DEVIATION					
SUBJECT#		SITE#	_ _		
	d at a dose other than t	5cmH₂O			
Please indica					
	unication error				
Decisio	n by clinical staff				
Other (p	please state):				
Participant in	n the usual care group	DID receive CPAF			
	ite the reason				
Randor	misation				
Commu	unication error				
Decisio	n by clinical staff				
Other (p	please state):				
Other protoc	ol deviation				
Other (please	state):				
PROTOCOL	DEVIATION				
Briefly describ	be the protocol deviation				
Name and sig	gnature:			Date:	