SECTION 1: INCLUSION, EXCLUSION & RANDOMISATION INFORMATION					
SUBJECT #					
DEMOGRAPHIC INFORMATION					
Given name	Family name	_ _ _		_ _ _	
Date of birth	Gender	Female		Male □	
Consent date	Date of surgery	_ /	_ <mark>/</mark> DD/MMM/YYYY)		
INCLUSION & EXCLUSION CRITERIA			YES	NO	
Age ≥ 50 years					
Planned elective major intra-peritoneal surgery using	g 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 care					
Known or suspected pregnancy or planned obstetric					
Previous enrolment in the PRISM trial					
Current participation in another clinical trial of a treat mechanism or primary outcome measure					
Clinician refusal (concern specific to surgical proced					
Clinician refusal (other)					
Contraindication to continuous positive airway press	ure (CPAP)				
Planned level of care on the first night after surg	ery		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 approp	riate)		TICK	OHE	
Resection of colon, rectum or small bowel	ilute)			7	
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	BEFORE SURGERY					
SUE	BJECT#	_ _ - - -	SITE#		_ _		
CO-	MORBID	DISEASE				YES	NO
1.	Chronic	respiratory disease					
	Chro	nic obstructive pulmonar	y disease (COP	D)			
	Asth	ma					
	Inter	stitial lung disease or pul	monary fibrosis				
	Bron	chiectasis					
2.	Ischaem	nic heart disease					
3.	Diabete	s mellitus					
4.	Heart fa	ilure					
5.	Liver cir	rhosis					
6.	Active c	ancer					
	If yes	s – is cancer the indication	on for surgery?				
		If yes - is the sur	gery intended to	be: ☐ curative	or □ pa	lliative	
7.	Previous	s stroke or transient isch	aemic attack (TI/	۹)			
8.	Current	smoker (within the last 1	4 days)?				
9.	tubercul		•	,			
10.	Diagnos please t	sis of Human Immunodef ick 'no'.	ciency Virus (HI	V) infection? NB. If no	ot tested		
	IER DET						
	onal ID nu		_				
ASA	-	an Society of Anesthesiol			01 1/5		
Dlan	Class		Class III	Class IV □	Class V □		_
•		surements	,	Moight (kg):		1 1	
neig	ht (cm):	ing oxygen saturation (S	nO).	Weight (kg):			

|__|__| g/dL

 $|_|_|$ μ mol/L

Black or Afro-Carribean □

Haemoglobin measurement

Creatinine measurement

Ethnicity (for eGFR)

Laboratory values (within 4 weeks before surgery)

Tick if NOT measured

Other \square

SECTION 3: DURING S	SURGERY							
SUBJECT # _ - _	_	SITE#		_ _ _				
START OF SURGERY	START OF SURGERY DATE: _ / _ / _ / /							
SURGICAL PROCEDURE	E PERFORM	MED (single most	appropriate)	Tick o	ne			
Resection of colon, rectun			, ,					
Resection of liver, pancrea	as or gall bla	dder						
Resection of stomach (nor	n-obesity su	rgery)						
Resection of oesophagus	(non-obesity	/)						
Obesity surgery		•						
Vascular procedure								
Other intra-peritoneal surgery								
SURGICAL TECHNIQUE	, ,			YES	NO			
Open surgical technique u	sed during s	surgery						
ANAESTHETIC TECHNIC	QUE							
General Anaesthesia								
Epidural anaesthesia								
Spinal anaesthesia								
Did the patient have an er	ndotracheal t	ube inserted?						
If YES, was the patient	extubated b	efore leaving the o	perating room?					
MECHANICAL VENTILAT	TION DURIN	IG SURGERY						
Did the patient receive a re	ecruitment n	nanoeuvre during s	surgery?					
Did the patient receive me	chanical ver	ntilation during sur	gery?					
If YES, please answer	-			T				
Maximum positive	end-expirato	ory pressure (PEEF	P)	_ CI	mH ₂ O			
Maximum set tidal volume (Vt) _ _				ml				
Maximum respiratory rate _ min				min ⁻¹				
Maximum FiO ₂ (ex	Maximum FiO ₂ (excluding pre-oxygenation during induction of anaesthesia) _ %							
INTRAVENOUS FLUIDS	DURING SU	IRGERY						
Total volume of intravenou	us fluid admi	nistered excluding	blood products		_ mL			
Total volume of blood prod	ducts admini	stered			_ mL			

Date and time of the end of surgery

SECTION 4	: IRIAL INTERVENTION	ON PERIOD				
SUBJECT#	_ - - -	SITE#				
CDAD AETE	D CUDCEDV			VEC	NO	
	R SURGERY	oitivo Aimvov Dros	cours (CDAD) started within	YES	NO	
•	after the end of surgery?	•	ssure (CPAP) started within			
	If YES, please answer th	ne following quest	ions. If NO, please skip to next s	section.		
Date and time	e patient started CPAP	_ _	_ / _ / _ / _ _	_ : (HR:M	_ IINS)	
Total duration	n of CPAP within twelve h	nours of the end o	of surgery	_ (MIN	_ NS)	
Maximum air	way pressure received d	uring this period			cmH ₂ O	
Primary meth	nod of CPAP delivery (sin	gle most appropri	iate)			
Face mas	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 mor	nitor airway pressures?			
Did the staff	administering CPAP use	equipment to mor	nitor the FiO ₂ ?			
Did the patie	nt have a nasogastric tub	e <i>in situ</i> during C	PAP?			
RESPIRATO	RY SUPPORT AFTER S	URGERY		YES	NO	
Did the patie	nt receive any of the follo	wing within four h	ours of the end of surgery?			
Invasive m	nechanical ventilation					
Non-invas	ive mechanical ventilatio	n				
High flow	nasal oxygen therapy					
LEVEL OF C	LEVEL OF CARE ON THE FIRST NIGHT AFTER SURGERY					
Critica	al care unit level 3					
Critica	al care unit level 2					
Post-a	anaesthesia care unit					
Surgio	cal ward					

SECTION 5: 30-DAY FO	OLLOW-U	P							
SUBJECT # _ -	_	SITE#	:	<u> </u>	_		.ll		
Date of follow-up					_ / _ DD-	_ _ / MMM-YYYY)	_ _ _		
					· · · · · · · · · · · · · · · · · · ·	<u> </u>			
All of the outcome	e in sectio	n 5 refer to t	he time	o ne	ariod with	in 30 days	of rand	omisatio	nn .
Primary outcome	YES	NO NO		o pe		yes, date			J11
Pneumonia						/ _		_	
FIIEUIIIOIIIA						(DD-MMM	I-YYYY)		
Endotracheal re-intubation					_	/ <u> </u> (DD-MMM	/ -YYYY)	_ _	
Death	☐ Alive	□ Dead	Date of death: _ / _ / _ _ _			_			
-						(,		
Respiratory complications	3		ı		II	III	IV	V	NONE
Pneumonia									
Pleural effusion									
Pneumothorax									
Bronchospasm									
Aspiration pneumonitis									
Acute Respiratory Distress S	Syndrome (ARDS)							
Infective complications			I		Н	III	IV	V	NONE
Surgical site infection (super	rficial)								
Surgical site infection (deep))								
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#						_ _	
Cardias sam	plications						11/	W	NONE
Cardiac com					II		IV	V	NONE
Myocardial inf Arrhythmia	rarction			<u> </u>					
	pulmonary oedema								
	t with successful resusci	tation							
Oditulae arres	t with 3docc33rdi re3d3ch	tation							
Other compl	ications		I		II	III	IV	V	NONE
Acute kidney									
Pulmonary er									
Stroke									
Acute psycho	sis or delirium								
Bowel infarcti	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:									
						1		1	
Additional tr	eatments							YES	NO
Blood transfu	ısion								
Parenteral (in	ntra-venous) nutrition								
Endoscopy o	r interventional radiology	procedure							
Repeat surge	ery								
If YES,	please indicate the reas	on for repeat	surgei	ry					
	Infection								
	Bleeding								
	Anastomotic leak								
	Other								
Invasive med	hanical ventilation after l	eaving the op	eratin	g ro	om				
If YES,	what was the total durat	ion of invasive	e mec	hani	cal ventila	tion?		_	hours

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

|__|_| hours

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

Patients admitted to a critical care unit	YES	NO
Was the participant admitted to a critical care unit? NB. If 'no', move to the next section.		
Was the critical care admission to treat a complication?		
Was a planned critical care admission prolonged by a postoperative complication?		
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	
Details of the hospital stay	YES	NO
Duration of primary hospital admission (from randomisation)		days
Re-admission to hospital within 30 days of randomisation		
Investigator self-assessment of blinding		
I was suitably blinded		

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-MIMIM-1111)	

☐ Alive ☐ Dead: date of death: |__|_|/|__|_|/|_(DD-MMM-YYYY)

SECTION 6: ONE-YEAR FOLLOW-UP

Patient status on date of 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:MINS)			
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	E 2		
Please descr	ibe the adverse event, in	cluding any treatme	ent or me	edication required.	
				Г	
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

ONLY COMPLETE THIS FORM IT THERE IS A PROTOCOL DEVIATION	714			
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				
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				
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				
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 5	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				
PROTOCOL DEVIATION Briefly describe the protocol deviation.					
Name and sig	 gnature:			Date:	