Oxy-Picu

Case Report Form (CRF)

Please ensure CRF stays with patient

Trial number

Treatment allocation

Target SpO_2: 88-92% (C)

Target SpO_2: >94% (L)

Date/time patient first met all eligibility criteria

Date: D D / M M / 2 0 2 Y Time: H H : M M (24-hour clock)

Definitions

Date/Time of final extubation	The first successful extubation – being extubated for at least 48 hours without reintubation.
Invasive respiratory support	Respiratory support delivered via either a endotracheal or tracheostomy tube.
Non-invasive respiratory support	Respiratory support delivered via nasopharyngeal airway, mask or nasal prongs and delivered by a mechanical device.
Date/time of end of all respiratory support	This includes all support with a machine – including HFNC or NIV – but not for oxygen alone. Use the end of the last period of support that started in the 30 days following randomisation, provided that all respiratory support had ended for at least 48 hours.
FiO_2	Record the FiO_2 being given at the time the arterial PaO_2 is measured and recorded.
Base excess	Indicate whether measurement is positive (+) or negative (-).
Pupil reaction	Only record as fixed if both pupils are >3mm and fixed and not caused by drugs, toxins or direct injury to the eye.
Organ support	Refer to 'Definitions: Organ Support' on page 16, which are based on PICANet definitions.
Adverse Event severity	**None**: indicates no event or complication **Mild**: complication results in only temporary harm and does not require clinical treatment **Moderate**: complication requires clinical treatment but does not result in significant prolongation of hospital stay. Does not usually result in permanent harm and where this does occur the harm does not cause functional limitation to the patient **Severe**: complication requires clinical treatment and results in significant prolongation of hospital stay and/or permanent functional limitation **Life-threatening**: complication that may lead to death or where the participant died as a direct result of the complication/adverse event

Guidance

Hourly observations	Record observations on the hour; this observation must be within 15 minutes (+/-) of the start of the hour. If no measurement is recorded within this timeframe, please enter 'M' for missing. If multiple/all measurements will not be recorded within timeframe – for example, if some measurements are only taken at specific times on your unit – please record measurements and note time taken. At the start of intervention, please record Y for 'invasive ventilation received' and note baseline measurements at the closest hour: *Example:* Where intervention begins at 03:29, start measurements at 03:00. Where intervention begins at 03:30, start measurements at 04:00. After Day 7, these observations move to twice daily (09:00 and 21:00) and must fall within 1 hour (+/-).
Daily and twice daily observations	Record observations daily (Hb, PaO_2) at 09:00 or twice daily (HR, Lactate) at 09:00 and 21:00. These observations must fall within 1 hour (+/-). Where intervention begins between 09:00 and 21:00, record observations from 21:00 on Day 1 onwards. Where intervention begins after 21:00, record observations from 09:00 on Day 2 onwards.
Observations beyond 30 days	Where a child remains invasively ventilated for more than 30 days, continue with daily/twice daily observations. Contact ICNARC for advice on specific patients.
Organ support	Please tick all types of organ support received per day for any length of time, or 'no support' if none. Days run from 00:00 to 23:59. Day 1 = day of randomisation; Day 2 = first calendar day following Day 1 from 00:00. Organ support observations are only required up to and including Day 30.
Not appropriate to approach for consent	Only mark that it was not appropriate to approach in exceptional circumstances (e.g. child is under the care of social services and an appropriate legal guardian cannot be identified). For specific guidance or if unsure of the most appropriate method to obtain consent, please contact the Oxy-PICU trial team. Telephone consent is acceptable as a temporary measure during the coronavirus pandemic.

Definitions (cont)

*If patient has died, PCPC/POPC on page 18 does not need to be completed.

For functional status at PICU discharge where a patient is admitted and discharged from PICU multiple times;
If within 30 days of randomisation, use the last discharge. Otherwise, use the first discharge after 30 days from randomisation.

Paediatric Cerebral Performance Category (PCPC)

The PCPC scale measures and quantifies effective morbidity after a child's critical illness or injury. PCPC focuses on cognitive impairment.

Score	Category	Description
1	Normal	Age-appropriate level of functioning Pre-school child: developmentally appropriate School-aged child: can attend regular school classroom
2	Mild disability	Conscious, alert and able to interact at age-appropriate level Pre-school child: may have minor developmental delays School-aged child: can attend regular classroom, but grade is not appropriate for age, or child is likely to fail appropriate grade because of cognitive difficulties
3	Moderate disability	Conscious, below age-appropriate functioning Neurologic disease that is not controlled and severely limits activities Pre-school child: delayed for most of their activities of daily living School-aged child: Sufficient cerebral function for age-appropriate independent activities of daily life, must attend special education classroom because of cognitive difficulties and/or learning deficits
4	Severe disability	Conscious Pre-school child: delayed for most of their activities of daily living and excessively dependent on others for the provision of activities of daily living School-aged child: may be so impaired as to be unable to attend school, dependent on others for daily support because of impaired brain function
5	Coma or vegetative state	Any degree of coma Unaware, even if awake in appearance, without interaction with environment Cerebral unresponsiveness and no evidence of cortical function (eg. not aroused by verbal stimuli) Possibility of some reflective response, spontaneous eye-opening and sleep-wake cycles

Paediatric Overall Performance Category (POPC)

The POPC scale measures and quantifies effective morbidity after a child's critical illness or injury, focusing on functional morbidity. POPC is dependent on PCPC scale as a result of inclusion of PCPC status in the operational definitions of the POPC scale categories.

Score	Category	Description
1	Good overall performance	PCPC score of 1 Healthy, alert and capable of normal age-appropriate activities of daily life Medical and physical problems do not interfere with normal activity
2	Mild overall disability	PCPC score of 2 Minor chronic physical or medical problems present minor limitations but are compatible with normal life (eg. asthma) Pre-school child: has a physical disability consistent with future independent functioning (eg. a single amputation) and is able to perform the majority of age-appropriate activities of daily living
3	Moderate overall disability	PCPC score of 3 Possibility of moderate disability from non-cerebral systems dysfunction alone or with cerebral system dysfunction Pre-school child: delayed for most of their activities of daily living School-aged child: conscious and performs independent activities of daily life but is physically disabled (eg. cannot participate in competitive physical activities)
4	Severe overall disability	PCPC score of 4 Possibility of severe disability from non-cerebral systems dysfunction alone or with cerebral system dysfunction Pre-school child: delayed for most of their activities of daily living and excessively dependent on others for the provision of activities of daily living School-aged child: dependent on others for most activities of daily living
5	Coma or vegetative state	PCPC score of 5

Baseline: Demographics/Observations

Trial number

Personal data need not be recorded until after consent is obtained. Until consent is obtained or refused, please do record at least PICANet number.

Demographics

First name:

Surname:

Sex: Male ◯ Female ◯

Hospital number:

Date of birth: D D / M M / Y Y Y Y

PICANet number:

NHS number:

Postcode:

Physiology/Interventions

Values should be recorded within one hour prior to randomisation. Enter 'NR' for Not Recorded in source data.

Last observations prior to randomisation

Arterial PaO_2: . kPa / mmHg *(Delete as appropriate)* Not recorded ◯

Base excess: +/- . $mmol\ l^{-1}$ ◯

→ Source: Arterial ◯ Capillary ◯ Venous ◯

Lactate: . $mmol\ l^{-1}$ ◯

→ Source: Arterial ◯ Capillary ◯ Venous ◯

Systolic blood pressure: kPa / mmHg *(Delete as appropriate)* Not recorded ◯

Mean Airway Pressure: . cmH_2O ◯

Pupil reaction:
- Both equal and reactive ◯
- Both fixed and dilated ◯
- Other reaction ◯
- Unknown ◯

If patient is ≤ 3 months old

Fetal haemoglobin (HbF): . g/L

Completed by: (print name)

Signature:

Date completed: D D / M M / 2 0 2 Y

Baseline: Comorbidities

Documented pre-existing conditions that existed in the 12 months preceding this admission to the PICU

Trial number

Oxy-PICU

Airway/Respiratory
(e.g. Chronic lung disease, Asthma)

Yes ○ No ○

Cardiac/Vascular
(e.g. Atrioventricular septal defect, Tetralogy of Fallot)

Yes ○ No ○

Neurological/Neuromuscular
(e.g. Cerebral Palsy, Spinal muscular atrophy)

Yes ○ No ○

Congenital/Genetic/Syndrome
(e.g. Trisomy 21, Dravet syndrome)

Yes ○ No ○

Gastro/Surgical
(e.g. Tracheo-oesophageal fistula, Gastoschisis)

Yes ○ No ○

Haematology/Oncology
(e.g. Acute leukaemia, Medulloblastoma)

Yes ○ No ○

Metabolic/Endrocrine
(e.g. Diabetes Type I, Hypothyroidism)

Yes ○ No ○

Immunodeficiency
(Characterised by a chronic state of a reduced ability to resist infection for at least three months as a result of a primary diagnosis, therapy or combination of both)

Yes ○ No ○

Other
If other, specify;

Yes ○ No ○

Completed by:
(print name)

Signature:

Date completed: D D / M M / 2 0 2 Y

Observations: Day 1

Trial number

Date and time of randomisation:

D	D	/	M	M	/	2	0	2	Y	H	H	:	M	M

	00:00	01:00	02:00	03:00	04:00	05:00	06:00	07:00	08:00	09:00	10:00	11:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												

Haemoglobin (g/L)	
PaO_2 (kPa / mmHg)	
Heart rate (bpm)	
Lactate (mmol l^{-1})	

(Delete unit as appropriate)

	12:00	13:00	14:00	15:00	16:00	17:00	18:00	19:00	20:00	21:00	22:00	23:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												

Heart rate (bpm)	
Lactate (mmol l^{-1})	

Signature: | **Completed by:** (print name) | **Date completed:** D D / M M / 2 0 2 Y

Observations: Day 2

Trial number

	00:00	01:00	02:00	03:00	04:00	05:00	06:00	07:00	08:00	09:00	10:00	11:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												

Haemoglobin (g/L)	
PaO_2 (kPa / mmHg)	
Heart rate (bpm)	
Lactate (mmol l^{-1})	

(Delete unit as appropriate)

	12:00	13:00	14:00	15:00	16:00	17:00	18:00	19:00	20:00	21:00	22:00	23:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												

Heart rate (bpm)	
Lactate (mmol l^{-1})	

Signature: | **Completed by:** (print name) | **Date completed:** D D / M M / 2 0 2 Y

Observations: Day 3

Trial number

	00:00	01:00	02:00	03:00	04:00	05:00	06:00	07:00	08:00	09:00	10:00	11:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												

Haemoglobin (g/L)	
PaO_2 (kPa / mmHg)	
Heart rate (bpm)	
Lactate (mmol l^{-1})	

(Delete unit as appropriate)

	12:00	13:00	14:00	15:00	16:00	17:00	18:00	19:00	20:00	21:00	22:00	23:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												

Heart rate (bpm)	
Lactate (mmol l^{-1})	

Signature: | **Completed by:** (print name) | **Date completed:** D D / M M / 2 0 2 Y

Observations: Day 4

Trial number

	00:00	01:00	02:00	03:00	04:00	05:00	06:00	07:00	08:00	09:00	10:00	11:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												

Haemoglobin (g/L)	
PaO_2 (kPa / mmHg)	
Heart rate (bpm)	
Lactate (mmol l^{-1})	

(Delete unit as appropriate)

	12:00	13:00	14:00	15:00	16:00	17:00	18:00	19:00	20:00	21:00	22:00	23:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												

Heart rate (bpm)	
Lactate (mmol l^{-1})	

Signature: | **Completed by:** (print name) | **Date completed:** D D / M M / 2 0 2 Y

Observations: Day 5

Trial number

	00:00	01:00	02:00	03:00	04:00	05:00	06:00	07:00	08:00	09:00	10:00	11:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												

Haemoglobin (g/L)	
PaO_2 (kPa / mmHg)	
Heart rate (bpm)	
Lactate (mmol l^{-1})	

(Delete unit as appropriate)

	12:00	13:00	14:00	15:00	16:00	17:00	18:00	19:00	20:00	21:00	22:00	23:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												

Heart rate (bpm)	
Lactate (mmol l^{-1})	

Signature: | **Completed by:** (print name) | **Date completed:** D D / M M / 2 0 2 Y

Observations: Day 6

Trial number

	00:00	01:00	02:00	03:00	04:00	05:00	06:00	07:00	08:00	09:00	10:00	11:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												

Haemoglobin (g/L)	
PaO_2 (kPa / mmHg)	
Heart rate (bpm)	
Lactate (mmol l^{-1})	

(Delete unit as appropriate)

	12:00	13:00	14:00	15:00	16:00	17:00	18:00	19:00	20:00	21:00	22:00	23:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												

Heart rate (bpm)	
Lactate (mmol l^{-1})	

Signature: | **Completed by:** (print name) | **Date completed:** D D / M M / 2 0 2 Y

Observations: Day 7

Trial number

	00:00	01:00	02:00	03:00	04:00	05:00	06:00	07:00	08:00	09:00	10:00	11:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												

Haemoglobin (g/L)	
PaO_2 (kPa / mmHg)	
Heart rate (bpm)	
Lactate (mmol l^{-1})	

(Delete unit as appropriate)

	12:00	13:00	14:00	15:00	16:00	17:00	18:00	19:00	20:00	21:00	22:00	23:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												

Heart rate (bpm)	
Lactate (mmol l^{-1})	

Signature: | **Completed by:** (print name) | **Date completed:** D D / M M / 2 0 2 Y

Observations: Days 8-19

Trial number

	Day 8		Day 9		Day 10		Day 11		Day 12		Day 13	
	09:00	21:00	09:00	21:00	09:00	21:00	09:00	21:00	09:00	21:00	09:00	21:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												
Heart rate (bpm)												
Lactate (mmol l^{-1})												
Haemoglobin (g/L)												
PaO_2 (kPa / mmHg) ***(Delete as appropriate)***												

	Day 14		Day 15		Day 16		Day 17		Day 18		Day 19	
	09:00	21:00	09:00	21:00	09:00	21:00	09:00	21:00	09:00	21:00	09:00	21:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												
Heart rate (bpm)												
Lactate (mmol l^{-1})												
Haemoglobin (g/L)												
PaO_2 (kPa / mmHg) ***(Delete as appropriate)***												

Signature: | **Completed by:** (print name) | **Date completed:** D D / M M / 2 0 2 Y

Observations: Days 20-30

Trial number

	Day 20		Day 21		Day 22		Day 23		Day 24		Day 25	
	09:00	21:00	09:00	21:00	09:00	21:00	09:00	21:00	09:00	21:00	09:00	21:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												
Heart rate (bpm)												
Lactate (mmol l^{-1})												
Haemoglobin (g/L)												
PaO_2 (kPa / mmHg) ***(Delete as appropriate)***												

	Day 26		Day 27		Day 28		Day 29		Day 30	
	09:00	21:00	09:00	21:00	09:00	21:00	09:00	21:00	09:00	21:00
Invasive ventilation received (Y/N)										
If yes:										
SpO_2 (%)										
Mean airway pressure (cmH_2O)										
FiO_2 (decimal)										
Heart rate (bpm)										
Lactate (mmol l^{-1})										
Haemoglobin (g/L)										
PaO_2 (kPa / mmHg) ***(Delete as appropriate)***										

Signature: | **Completed by:** (print name) | **Date completed:** D D / M M / 2 0 2 Y

Observations: Days 31+

Trial number

Date: DD/MM/YYYY	Day __		Day __		Day __		Day __		Day __		Day __	
	09:00	21:00	09:00	21:00	09:00	21:00	09:00	21:00	09:00	21:00	09:00	21:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												
Heart rate (bpm)												
Lactate ($mmol\ l^{-1}$)												
Haemoglobin (g/L)												
PaO_2 (kPa / mmHg) ***(Delete as appropriate)***												

	Day __		Day __		Day __		Day __		Day __		Day __	
	09:00	21:00	09:00	21:00	09:00	21:00	09:00	21:00	09:00	21:00	09:00	21:00
Invasive ventilation received (Y/N)												
If yes:												
SpO_2 (%)												
Mean airway pressure (cmH_2O)												
FiO_2 (decimal)												
Heart rate (bpm)												
Lactate ($mmol\ l^{-1}$)												
Haemoglobin (g/L)												
PaO_2 (kPa / mmHg) ***(Delete as appropriate)***												

Signature: | **Completed by:** (print name) | **Date completed:** D D / M M / 2 0 2 Y

Daily observations

Organ support

Trial number

Record until patient is discharged home, or up to Day 30 following randomisation; whichever is sooner. Please continue to record this even if patient has been discharged from critical care (eg. to ward).

Please tick all types of organ support a patient receives on a given day for any length of time, or 'no support' if none.
Day 1 = day of randomisation, Day 2 = first calendar day following Day 1, etc.

DEFINITIONS: ORGAN SUPPORT

Respiratory
- Any non-invasive respiratory support
- Advanced ventilatory support

(**Do not include** nasopharyngeal airway, or supplemental oxygen therapy alone, as organ support)

Cardiovascular
- Continuous inotrope/vasodilator/ prostaglandin infusion
- Bolus IV fluids in addition to maintenance IV fluids
- CPR
- ECMO
- Vascular assist device
- Aortic balloon pump
- Anti-arrhythmic therapy

Renal
- Peritoneal dialysis
- Haemofiltration
- Haemodialysis
- Plasma filtration
- Plasma exchange

Other
- Neurological;
  - Intraventricular catheter
  - External ventricular drain
  - Continuous infusion of anti-epileptic drugs
- Analgesia/sedation;
  - Epidural catheter
  - Continuous intravenous infusion of a sedative agent
- Metabolic;
  - Continuous infusion of insulin
- Exchange transfusion
- Intravenous thrombolysis
- MARS

Organ support:		Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15
No support																
Respiratory	Invasive respiratory support															
	Any NIV (including HFNC)															
Cardiovascular																
Renal																
Other	Continuous infusion of sedative agent															
	Blood transfusion															
	Any other															

Organ support:		Day 16	Day 17	Day 18	Day 19	Day 20	Day 21	Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28	Day 29	Day 30
No support																
Respiratory	Invasive respiratory support															
	Any NIV (including HFNC)															
Cardiovascular																
Renal																
Other	Continuous infusion of sedative agent															
	Blood transfusion															
	Any other															

Signature: | **Completed by:** (print name) | **Date completed:** D D / M M / 2 0 2 Y

Outcome

Trial number

Oxy-Picu

Liberation from ventilation

Date/time of final extubation: D D / M M / 2 0 Y Y H H : M M (24-hour clock)

Date/time of end of all respiratory support: D D / M M / 2 0 Y Y H H : M M (24-hour clock)

Discharge from your critical care unit

Status: ◯ Alive ◯ Dead

Date/Time: D D / M M / 2 0 Y Y H H : M M (24-hour clock)

Discharge Method *(tick one)*

- ◯ Patient discharged on clinical advice or with clinical consent
- ◯ Patient discharged themselves
- ◯ Patient was discharged by a relative or advocate
- ◯ Patient discharged by mental health review tribunal, Home Secretary or Court
- ◯ Patient died
- ◯ Unknown

Ultimate discharge from critical care (if transferred to another critical care unit)

Transferred to another critical care unit: ◯ Yes ◯ No Status: ◯ Alive ◯ Dead

Date/Time: D D / M M / 2 0 Y Y H H : M M (24-hour clock)

Locations of care (after discharge from your critical care to ultimate acute hospital discharge)

Location*:	Date of admission:
	D D / M M / 2 0 Y Y
	D D / M M / 2 0 Y Y
	D D / M M / 2 0 Y Y
	D D / M M / 2 0 Y Y
	D D / M M / 2 0 Y Y
	D D / M M / 2 0 Y Y

Location:

P = PICU
H = HDU
C = Combined ICU/HDU
W = Ward
T = In Transport

Ultimate discharge from acute hospital

Status: ◯ Alive ◯ Dead

Date: D D / M M / 2 0 Y Y

Death after hospital discharge

Date of death: D D / M M / 2 0 Y Y

Co-enrolment(s)

Please record any other interventional trials to which the patient was enrolled

Completed by: (print name)

Signature:

Date completed: D D / M M / 2 0 2 Y

Outcome (cont)

Functional status at PICU discharge

Trial number

Oxy-PICU

See Definitions page for more details on POPC and PCPC.

If a patient is admitted and discharged from PICU multiple times;
If within 30 days of randomisation, use the last discharge. Otherwise, use the first discharge after 30 days from randomisation.

***If patient has died, this page does not need to be completed.**

Paediatric Cerebral Performance Category (PCPC)

Score:	Description:
1	**Good overall performance** – At age-appropriate level; school-aged child can attend regular school
2	**Mild overall disability** – Conscious, alert, able to interact at age-appropriate level; school-aged child can attend regular school, but grades perhaps not age-appropriate, possibility of mild neurologic defect
3	**Moderate overall disability** – Conscious, age-appropriate independent activities of daily life; school-aged child likely to require special education classroom, learning deficit present
4	**Severe overall disability** – Conscious, dependent on others for daily support because of impaired brain function
5	**Coma or vegetative state** – Any degree of coma; unaware, even if awake in appearance, without interaction with the environment; no evidence of cortex function; possibility for some reflexive response, spontaneous eye-opening, sleep-wake cycles

Paediatric Overall Performance Category (POPC)

Score:	Description:
1	**Good overall performance** – PCPC1; healthy, alert and capable of normal activities of daily life
2	**Mild overall disability** – PCPC2; possibility of minor physical problem still compatible with normal life
3	**Moderate overall disability** – PCPC3; possibility of moderate disability from non cerebral systems dysfunction alone or with cerebral dysfunction; performs independent activities of daily life but disabled for competitive performance at school
4	**Severe overall disability** – PCPC4; possibility of severe disability from non cerebral systems dysfunction alone or with cerebral dysfunction; conscious but dependent on others for activities of daily living support
5	**Coma or vegetative state** – PCPC5

Completed by: (print name)

Signature:

Date completed: D D / M M / 2 0 2 Y

Consent/Assent

Trial number

Oxy-PICU

Consent

Approached for consent (tick all that apply):

In person (F) By post (P)

Deemed not appropriate for approach (state reason) (N)

If postal approach:

Date of phone call D D / M M / 2 0 2 Y

Date of 1st postal approach D D / M M / 2 0 2 Y

Date of 2nd postal approach D D / M M / 2 0 2 Y

If in person:

Date first approached D D / M M / 2 0 2 Y

Response received Yes (Y) No (N)

Consent obtained for:

Trial continuation	Yes (Y)	No (N)
Access to medical records	Yes (Y)	No (N)
Follow-up questionnaire	Yes (Y)	No (N)
Sharing of anonymised data	Yes (Y)	No (N)
Future research	Yes (Y)	No (N)

Parents/guardian details:

Title First name

Surname

Phone/mobile

Contact preference Email (E) Phone (T) Post (P)

If email follow-up, email address:

If postal follow-up, address:

Date consent provided/declined D D / M M / 2 0 2 Y

Date of withdrawal of consent D D / M M / 2 0 2 Y

Reason for non-consent/withdrawal (if provided)

Assent

Approached for assent	Yes (Y)	No (N)
Assent given	Yes (Y)	No (N)

Date assent provided/declined D D / M M / 2 0 2 Y

If no:

Child <8 years (Y)

Child too sick (S)

Other (please state) (O)

Completed by: (print name)

Signature:

Date completed: D D / M M / 2 0 2 Y

Safety Monitoring

Trial number

Occurrences of the specified, expected adverse events will be recorded for all randomised patients from the time of randomisation until 30 days after randomisation or discharge from PICU, whichever is later.

Adverse events (specified)*

	Severity:	Start date:	Start time: (24-hour clock)	Related:
Severe lactic acidosis:		D D / M M / 2 0 2 Y	H H : M M	
Cardiac ischaemia:		D D / M M / 2 0 2 Y	H H : M M	
Acute kidney injury:		D D / M M / 2 0 2 Y	H H : M M	
Seizures:		D D / M M / 2 0 2 Y	H H : M M	

***If specified adverse events occur more than once, please record in 'other' (below)**
Please refer to SOP 008 Safety Monitoring for adverse event definitions

Adverse events (other)**

Adverse event:	Severity:	Start date:	Start time: (24-hour clock)	Related:
		D D / M M / 2 0 2 Y	H H : M M	
		D D / M M / 2 0 2 Y	H H : M M	
		D D / M M / 2 0 2 Y	H H : M M	
		D D / M M / 2 0 2 Y	H H : M M	
		D D / M M / 2 0 2 Y	H H : M M	
		D D / M M / 2 0 2 Y	H H : M M	
		D D / M M / 2 0 2 Y	H H : M M	
		D D / M M / 2 0 2 Y	H H : M M	
		D D / M M / 2 0 2 Y	H H : M M	
		D D / M M / 2 0 2 Y	H H : M M	

****Only record adverse events with a relatedness of 'possibly' or higher.**
Always record additional specified adverse events (see above) under other adverse events regardless of Relatedness

Severity 0 = None, 1 = Mild, 2 = Moderate, 3 = Severe, 4 = Life threatening

Related: 0 = Not related, 1 = Unlikely, 2 = Possibly, 3 = Probably, 4 = Definitely

If severity of adverse event (specified or other) is:

3 = Severe or 4 = Life threatening

Please complete the Serious Adverse Event Reporting Form and email to ICNARC or upload to eCRF within 24 hours. Please also enter the information in MACRO on the SAE page.

Completed by: (print name)

Signature:

Date completed: D D / M M / 2 0 2 Y