Serious Adverse Event (SAE) Reporting Form

Please complete all sections with details of any SAE occurring from randomisation until 30 days after randomisation or discharge from PICU, whichever is later. For guidance on which events to report please see study protocol and SOP 008 – Safety monitoring. **Please send this form to the ICNARC CTU within 24 hours of notification of the event.**

Study details			
Study title:	**A Randomised Multiple Centre Trial of Conservative versus Liberal Oxygenation Targets in Critically Ill Children**	**REC reference:**	19/EE/0362

Patient details			
Patient trial number:	☐☐☐☐☐	**Study arm:**	☐ **Target SpO_2: 88-92%**
Age:	☐☐ days / weeks / months / years		☐ **Target SpO2: >94%**
Site name:		**Treating Clinician:**	
Type of report:	☐ First ☐ Update ☐ Final		

	Start date d d m m y y	**Start time** 24-hour clock	**End date** d d m m y y	**End time** 24-hour clock
Study SpO2 target	☐☐ ☐☐ ☐☐	☐☐:☐☐	☐☐ ☐☐ ☐☐	☐☐:☐☐

Event summary description *(Give a concise medical description of all relevant symptoms, and complete page overleaf)*	Continued on a separate sheet: ☐ **Y** ☐ **N**
No. of events included in this report: ☐	

Any relevant medical history / concurrent conditions? ☐ **Y** ☐ **N** *(If yes, please specify below)*	
	Was event expected in view of patient's medical history? ☐ **Y** ☐ **N**

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Patient trial number: ☐☐☐☐☐

Serious Adverse Event (SAE)

COMPLETE A SEPARATE PAGE FOR EACH EVENT THAT MEETS THE DEFINITION OF SERIOUS (photocopy this page as necessary for each event)

Name of event	Severity 1 = Mild 2 = Moderate 3 = Severe 4 = Life threatening 5 = Fatal	Start date d d m m y y	Start time 24-hour clock	Date resolved d d m m y y
	☐	☐☐ ☐☐ ☐☐	☐☐ : ☐☐	☐☐ ☐☐ ☐☐

Why was the event serious *(tick all that apply)*				Outcome			
☐	Resulted in death	☐	Life-threatening	☐	Resolved	☐	Resolved with sequelae
☐	Required new or prolonged hospitalisation	☐	Resulted in persistent or significant disability/incapacity	☐	Persisting	☐	Worsened
☐	Resulted in congenital anomaly/birth defect	☐	Other (*specify*) _____	☐	Fatal	☐	Not assessable

SAE Assessment

	Relationship to event *(Enter <u>one</u> code only)* 0 = None 1 = Unlikely 2 = Possibly 3 = Probably 4 = Definitely	Event expected for the study treatment *(Enter <u>one</u> code only)* 1 = Expected 2 = Not Expected	Action taken: SpO2 target *(Enter <u>one</u> code only)* 0 = None 1 = Increased SpO_2 target 2 = Decreased SpO_2 target	Action taken: Changes to Respiratory Support *(Enter <u>one</u> code only)* 0 = None 1 = Increased FiO2 and/or MAP 2 = Decreased FiO2 and/or MAP 3 = Other change to respiratory support (specify)	Is action taken re: SpO2 target: *(Enter <u>one</u> code only or N/A)* 1 = Temporary 2 = Permanent	Provide reason for action taken
Study SpO_2 target:	☐	☐	☐	☐	☐	

Signature: PI or other delegated personnel only		Print name:		Date of report:	☐☐ ☐☐ ☐☐ d d m m y y

Office use only

Checked by	Print name:	_____	Signature:	_____	Date: ☐☐ ☐☐ ☐☐ (d d m m y y)
Reviewed by	Print name:	_____	Signature:	_____	Date: ☐☐ ☐☐ ☐☐ (d d m m y y)