SERIOUS ADVERSE EVENT (SAE) REPORTING FORM

Please put a tick in either the Yes OR No box for each question. Please answer all questions.

Has the patient experienced any Serious Adverse Events since Randomisation? ☐$_1$ Yes ☐$_0$ No

TRIAL DETAILS		SITE DETAILS	
Protocol Acronym: REST		**Site Number:**	
		Patient Number:	
Protocol No.: 15084DMcA-AS		**Patient Initials:**	

SERIOUS ADVERSE EVENT TIMELINE

Date of onset of Adverse Event (AE): D D / M M / Y Y Y Y

Date event fulfilled criteria for Seriousness: D D / M M / Y Y Y Y

Serious adverse event term:

Please ensure that there is a corresponding AE completed for this patient in the MACRO database **and** ***that the SAE Term is consistent with that listed for the corresponding Adverse Event***

Date team became aware of event: D D / M M / Y Y Y Y

Time team became aware of event (Please ensure this is recorded in 24 hour clock): H H : M M

Was there a delay in reporting the SAE? ☐$_1$ **Yes** ☐$_0$ **No**

If yes please provide reason:

Is this event ongoing* ☐$_1$ **Yes** ☐$_0$ **No**

If yes, please resubmit the SAE Reporting form with the date event resolved completed. Please note should the patient die prior to resolution; the event will remain as ongoing.

Date event resolved: D D / M M / Y Y Y Y

DESCRIPTION OF EVENT: Including symptoms, diagnostic investigations, results and any other additional information.

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REASON EVENT CLASSIFIED AS SERIOUS:	
☐ 1	Led to a death
☐ 2	Resulted in a life-threatening illness or injury
☐ 3	Resulted in a permanent impairment of a body structure or a body function
☐ 4	Required inpatient hospitalisation or prolongation of existing hospitalisation
☐ 5	Resulted in medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function
☐ 6	Led to foetal distress, foetal death or a congenital abnormality or birth defect.

** If resulted in death, please record Date of Death and complete Death report Form in the EDC system:* D D / M M / Y Y Y Y

Please note that the Expectedness is only to be completed if Causality is Possibly, Probably or Definitely.

SEVERITY	
☐ 1	1=Mild
☐ 2	2=Moderate
☐ 3	3=Severe
☐ 4	4=Life threatening
☐ 5	5=Fatal

CAUSALITY	
☐ 1	1=Not assessable
☐ 2	2=Not related
☐ 3	3=Unlikely
☐ 4	4=Possibly
☐ 5	5=Probably
☐ 6	6=Definitely

EXPECTEDNESS	
☐ 1	1=Expected
☐ 2	2=Unexpected

DETAILS Of THE INVESTIGATOR ASSESSING EVENT:

Print Name:	Signature:	Date Completed:
		D D / M M / Y Y Y Y

Serious Adverse Device Effect (SADE) is defined as adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.
Unanticipated Serious Adverse Device Effect (USADE) serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.
NOTE: Anticipated: an effect which by its nature, incidence, severity or outcome has been previously identified in the list of expected adverse events

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STUDY INTERVENTION ACTION TAKEN

☐0 None

☐1 Stopped - e.g. removal of the device

☐2 Interrupted for therapy e.g. re-establishing conventional ventilation, or decreasing/stopping CO2 removal

☐3 Other

Other, please specify:

If Intervention was stopped please indicate date : D D / M M / Y Y Y Y

CONCOMITANT MEDICATIONS

Please record details of all concomitant medications administered at the time of the event, including dates of administration. Exclude those used to treat the reaction.

Drug Name	Start Date			Stop Date			Ongoing?
	DD	MM	YY	DD	MM	YY	☐
	DD	MM	YY	DD	MM	YY	☐
	DD	MM	YY	DD	MM	YY	☐
	DD	MM	YY	DD	MM	YY	☐
	DD	MM	YY	DD	MM	YY	☐
	DD	MM	YY	DD	MM	YY	☐
	DD	MM	YY	DD	MM	YY	☐
	DD	MM	YY	DD	MM	YY	☐
	DD	MM	YY	DD	MM	YY	☐
	DD	MM	YY	DD	MM	YY	☐
	DD	MM	YY	DD	MM	YY	☐
	DD	MM	YY	DD	MM	YY	☐
	DD	MM	YY	DD	MM	YY	☐
	DD	MM	YY	DD	MM	YY	☐
	DD	MM	YY	DD	MM	YY	☐

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Please put a tick in either the Yes OR No box for each question. Please answer all questions.

ADDITIONAL INFORMATION

Was the Intervention administered as per protocol? ☐$_1$ **Yes** ☐$_0$ **No**

If no, please complete the Protocol Deviation Form

Was the patient withdrawn from the study as a result of this event? ☐$_1$ **Yes** ☐$_0$ **No**

If yes, please complete the Off-Study Form

RELEVANT MEDICAL HISTORY

ANY OTHER RELEVANT INFORMATION

REPORTER'S DETAILS

Print Name	Signature:	Date Completed:
		D D / M M / Y Y Y Y

Please note the Reporter must be an authorised health professional

YOU MUST COMPLETE THE SAE REPORT FORM AND SEND TO THE NI CLINICAL TRIALS UNIT (NICTU) OFFICE WITHIN 24 HOURS OF BECOMING AWARE OF THE EVENT.

Please forward form by email to : clinicaltrials@nictu.hscni.net

For NICTU Use Only

Date Report Received by NICTU:	Received by:
D D / M M / Y Y Y Y	