TRIAL OFFICE USE: | *Received:* | *Initial:* | *Checked:* | *Initial:*

Form number: 09

RECOVERY-RS
RESPIRATORY SUPPORT

Serious Adverse Event Form—Follow-up

SAE Reference no.
For trial office use only

TNO: ☐☐☐☐ **Age at onset:** ☐☐☐ **Site:**

Please email immediately to the RECOVERY-RS Coordinating Centre to:
WCTUQA@warwick.ac.uk & RECOVERY-RS@warwick.ac.uk

A. THIS REPORT RELATES TO THE ADVERSE EVENT DEEMED SERIOUS ON: d d – m o n – y y y y

(Date must match to that stated On part B of Initial Report)

B. FURTHER DETAILS OF EVENT:

1. Have there been any additional serious adverse event symptoms or worsening in grade of the event symptoms reported on the initial report?

Yes ☐ **No** ☐ → *Please continue to next page.*

Please complete part 2 below with any new or updated information.

Please include all relevant further details of the event, any additional tests performed, updated results and treatment:

_____
_____
_____
_____
_____
_____
_____
_____ *(Please continue on SAE Continuation Form as necessary)*

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C. CAUSALITY:

1. Was the event related to administration of the trial procedures?

☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Unrelated

2. Has the participant withdrawn from participation in the intervention due to this SAE: **No** ☐ **Yes** ☐

D. OUTCOME OF EVENT: *(please select one only)*

1. Resolved—no sequelae ☐ → **Date of resolution:** d d – m o n – y y y y **Time of resolution:** *24 hour clock* ☐☐ : ☐☐

2. Resolved— with sequelae ☐ → **Details of sequelae:** _____ Date of resolution: d d – m o n – y y y y

Time of resolution: ☐☐ : ☐☐ *24 hour clock*

3. Unresolved ☐ → Please complete another SAE Follow-up Form when appropriate

4. Death ☐

5. Unresolved at time of death/withdrawal ☐ → Please complete a Withdrawal Form if appropriate

Clinician assessing causality (print name): _____

(Please note: your must have read appropriate training slides and signed online training form) prior to completing SAE form)

Signature: _____ **Date signed:** d d – m o n – y y y y

Form completed by (print name): _____

Signature: _____ **Date signed:** d d – m o n – y y y y

TRIAL OFFICE USE:

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Completion Guidelines for Serious Adverse Event Form—Follow-up report

Form dates: Use format: 0 6 - J U N - 1 9 5 6

Further details of event: Please add any additional **relevant** information that has come to light since the initial report

Was the event related to administration of the study procedures?

Unrelated:	There is no evidence of any causal relationship
Unlikely:	There is little evidence to suggest a causal relationship (e.g. because the event did not occur within a reasonable time after administration of the trial treatment). There is another reasonable explanation of the event (e.g. the participants's clinical condition, other concomitant medications).
Possibly:	There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the trial treatment). However, the influence of other factors may have contributed to the event (e.g. the participants's clinical condition, other concomitant medications).
Probably:	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
Definitely:	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.