Form number: 11

Serious Adverse Event Form—Follow-up

iRehab
Remote rehabilitation after intensive care

Participant Trial Number: ☐☐☐☐ **Participant Initials:** ☐☐ **Age at Onset:** ☐☐☐

Randomising Site:

*Send a copy to WCTU trial team (irehab@warwick.ac.uk) and WCTU QA Team (wctuqa@warwick.ac.uk) **within 24 hours** of becoming aware of the event*

A. THIS REPORT RELATES TO THE ADVERSE EVENT DEEMED SERIOUS ON: d d – m m m – y y y y (Date must match to that stated in Section B. of Initial Report)

B. Have there been any additional serious adverse event symptoms or worsening in grade of the event symptoms reported on the initial report? ☐ **Yes,** *please complete section C* ☐ **No**, *please continue to next page.*

C. FURTHER DETAILS OF EVENT:

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)

D. CAUSALITY:

In the opinion of the reporting clinician,

1. Was the event related to the trial activity?

(Causality should be assessed and initialled by clinician)

☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Unrelated

☐ *Clinicians initials*

2. Has the participant withdrawn from participation in the intervention due to this SAE?

No ☐ **Yes** ☐

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

1. Resolved—no sequelae ☐ → **Date of resolution:** d d - m m m - y y y y

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

3. Unresolved ☐ → Please complete the SAE Follow up Form as appropriate

4. Death ☐ → Please complete notification of death form

5. Unresolved at time of death/withdrawal ☐ → Please complete notification of death/withdrawal form as appropriate

Reporting Clinician (print name): _____

(Please note: your name must be on the trial delegation log)

Signature: _____ **Date signed:** d d - m m m - y y y y

Form completed by (print name): _____

Signature: _____ **Date signed:** d d - m m m - y y y y

Completion Guidelines for CRF 11 Serious Adverse Event Form—Follow-up report

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

In the opinion of the reporting clinician...was the event related to the trial intervention?

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 participant'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 participant'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.

The SAE Follow-Up Form must be signed and dated by individuals who have been delegated the responsibility for completing the SAE Form and the Clinician responsible for SAE attribution; the signatures must be clearly reported on your Site Signature and Delegation Log.