Form number: 9

Serious Adverse Event Form—Initial

iRehab
Remote rehabilitation after intensive care

Participant Trial Number: ☐☐☐☐ **Participant Initials:** ☐☐ **SAE Reference No:** ☐☐☐

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. EVENT TYPE: *(please confirm 'Yes' or 'No' for each category)*

	No	Yes
1. Death	☐	☐
2. Life-threatening	☐	☐
3. Hospitalisation or prolongation of existing hospitalisation	☐	☐
4. Persistent or significant disability/incapacity	☐	☐
5. Congenital anomaly/birth defect	☐	☐
6. Requires medical intervention to prevent one of the above, or it is otherwise medically significant *(please specify below)*	☐	☐

B. EVENT DETAILS:

1. SAE Start Date d d – m m m – y y y y

2. Date Research Team Aware: d d – m m m – y y y y

C. Details of Event

i. Please include all **relevant** details of the event, any tests performed and associated results:

(Please continue on SAE Continuation Form as necessary)

ii. Please add details of any **relevant** medical history, medication and associated dates of administration:

(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 Has the participant withdrawn from participation in the intervention due to this SAE?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 9 Serious Adverse Event Form

Date Deemed Serious	This is the date when an adverse event is considered to be serious i.e. date the AE fitted one of the event types in box 1 to become categorised as a SAE
Date site became aware of the event	Please enter the date the investigator team at site first became aware of this event—this may be different from the date the event was deemed to be serious. N.B. GCP requires that investigators report all SAEs to the trial sponsor 'immediately' or at least within 24 hours of their first knowledge of the event

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 patient'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 patient'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.

All **SAEs** (unless otherwise specified) occurring from the time of **informed consent** until 8 weeks post randomisation and during the 8 week and 6-month outcome assessment appointments, must be recorded/reported accordingly.

SAEs exempt from reporting:

- Hospitalisation, or death, for pre-existing conditions e.g. respiratory exacerbation and infection, or a complication related to the initial ICU admission
- Treatment, which was elective or pre-planned, for a pre-existing condition, not associated with any deterioration in condition

The initial SAE must be signed and dated by both 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.