

# Serious Adverse Event Form—Follow-up

Participant Trial Number:

Participant Initials:

Age at Onset:

Randomising Site:

*Please email immediately to the ADAPT-Sepsis Coordinating Centre at [adaptsepsistrial@warwick.ac.uk](mailto:adaptsepsistrial@warwick.ac.uk)*

**A. THIS REPORT RELATES TO THE ADVERSE EVENT DEEMED SERIOUS ON:**
   -     -    

(Date must match to that stated in Section B. of Initial Report)

**B. FURTHER DETAILS OF EVENT:**

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

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

**C. SEVERITY ASSESSMENT:**

- Mild—Does not interfere with patient’s usual functioning
- Moderate—Interferes to some extent with patient’s usual functioning
- Severe—Interferes significantly with patient’s usual functioning
- Fatal/Life threatening— Causes death or risk of death, organ damage or disability

**D. CAUSALITY:**

In the opinion of the reporting clinician...

1. Was the event related to the trial intervention?

*(Causality should be assessed and initialled by clinician)*

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input style="width: 100%;" type="text"/>
Definitely	Probably	Possibly	Unlikely	Unrelated	Clinicians initials

Please continue to question E
Please skip question E and continue to question F

**E. EXPECTEDNESS:**

1. Was the event?

Expected:

Unexpected:

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

1. Resolved—no sequelae

Date of resolution:

  -    -    

2. Resolved— with sequelae

Details of sequelae:

Date of resolution:

  -    -    

3. Unresolved

Please complete the SAE Follow-up Form as appropriate

4. Death

Please complete notification of death form

Reporting Clinician (print name): \_\_\_\_\_

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

Signature: \_\_\_\_\_

Date signed:   -    -

Form completed by (print name): \_\_\_\_\_

Signature: \_\_\_\_\_

Date signed:   -    -

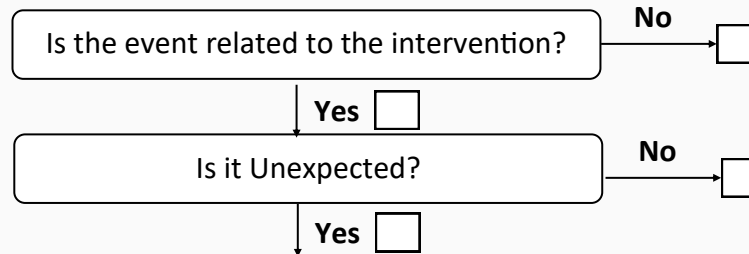
**SAE EVALUATION FORM (for Trial Office use only)**

Date adverse event information was passed to CI:   -    -

Were further investigations requested by CI? **No**  **Yes**  → Date further investigations carried out:   -    -

Details of investigations:

Date findings of further investigations passed to CI:   -    -



Date report sent to MREC/MHRA/sponsor (within 15 days of sponsor first aware of event):   -    -

Chief Investigators signature: \_\_\_\_\_

-    -

**Completion Guidelines for CRF 14 Serious Adverse Event Form—Follow-up report**

Date of Birth: Please use the following formats for dates: 06/Jun/1956.

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 Continuation Sheet must be signed and dated by both the person who has responsibility for completing the SAE Form and the Clinician responsible for SAE attribution; the signatures must appear on your Site Signature and Delegation Log.**