

Received Date:  Initial:

Checked Date:  Initial:

SAE Reference Number:

# Serious Adverse Event Continuation Form



Participant Trial Number:

Participant Initials:

Date of Birth:  -  -

Gender:  F  M

Site Number:

Site Name:

Please email immediately to the STRESS-L Coordinating Centre on [wctuqa@warwick.ac.uk](mailto:wctuqa@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)

Linked to: Initial Report  Follow-up Report

SAE form section number:	Additional information (according to section)

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:  -  -

## **Completion Guidelines for CRF 15 Serious Adverse Event Continuation Form**

### **Please complete this form if you run out of space on either Initial or Follow-up SAE forms**

At the top of the form is a space to write the date that the event became serious according to the original SAE form. This date must match the date on the original form so we are able to match up the additional information to the correct event. Please also indicate if this is a continuation of the initial report or the follow-up report.

**SAE Form section no:** The sections on the original SAE form are numbered from 1-5. Write in this box the number of the section for which the additional information applies.

**Additional information (according to section):** This section allows you to write the additional information you have about the SAE. Please give the information in the format suggested on the original SAE form.

**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.**