



Serious Adverse Event (SAE) Report

Area No	Site No	Participant I.D.	Participant initials
---------	---------	------------------	----------------------

URGENT - FAX FORM TO NCTU, NEWCASTLE-UPON-TYNE ON 0191 222 8901

1. REPORT TYPE: INITIAL FOLLOW-UP

SUBJECT DETAILS: (please see notes on page 3 on ethnicity codes for this form)

2. HEIGHT (cm):	3. ETHNICITY CODE	4. WEIGHT (kg):	5. DATE OF BIRTH						
[]	[]	[]	<table border="1"> <tr> <td style="width: 15%;">Day</td> <td style="width: 15%;">Month</td> <td style="width: 15%;">Year</td> </tr> <tr> <td>[]</td> <td>[]</td> <td>[]</td> </tr> </table>	Day	Month	Year	[]	[]	[]
Day	Month	Year							
[]	[]	[]							

SERIOUS ADVERSE EVENT (SAE) DETAILS:

6. SAE IN MEDICAL TERMS (DIAGNOSIS IF POSSIBLE):

7. CASE DESCRIPTION OF ABOVE SAE: (include related signs/ symptoms, suspected cause, record any information on changes or modifications to the intervention – please continue on separate page if required)

8. ONSET OF FIRST SIGN/SYMPTOM OF SAE:	ONSET TIME (IF KNOWN)	9. SEVERITY:												
<table border="1"> <tr> <td>[]</td> <td>[]</td> <td>[]</td> <td>[]</td> </tr> <tr> <td>Day</td> <td>Month</td> <td>Year</td> </tr> </table>	[]	[]	[]	[]	Day	Month	Year	<table border="1"> <tr> <td>[]</td> <td>[]</td> <td>[]</td> </tr> <tr> <td>Hour</td> <td>Minutes</td> </tr> </table>	[]	[]	[]	Hour	Minutes	<input type="checkbox"/> 1 = MILD <input type="checkbox"/> 2 = MODERATE <input type="checkbox"/> 3 = SEVERE
[]	[]	[]	[]											
Day	Month	Year												
[]	[]	[]												
Hour	Minutes													

10. SERIOUSNESS:	11. OUTCOME OF SAE:
<input type="checkbox"/> Subject died AND/OR <input type="checkbox"/> See key below and insert all appropriate number(s) for SAE (may be more than one)	<input type="checkbox"/> Completely Recovered (enter date of recovery below): OR <input type="checkbox"/> See key below and insert appropriate number.

- | | |
|---|--|
| 1 = Life-threatening
2 = Involved or Prolonged inpatient hospitalisation
3 = Involved persistent or significant disability or incapacity
4 = Other significant medical event | 5 = Recovered with sequelae
6 = Condition improving
7 = Condition still present & unchanged
8 = Condition deteriorated
9 = Death (if yes, provide autopsy report if autopsy performed) |
|---|--|

12. RELEVANT MEDICAL HISTORY: (including allergy, drug or alcohol abuse, family history)



**Serious Adverse
Event (SAE) Report**

Area No	Site No	Participant I.D.	Participant initials
---------	---------	------------------	----------------------

18. ASSESSMENT OF CAUSALITY (requires medical decision). In your medical judgement, is there a reasonable possibility that the event may have been caused by the trial intervention ?

YES OR NO

Expected OR Unexpected

NOTE - If causality is "YES" for trial intervention, please also indicate whether the nature or severity of SAE is "expected" or "unexpected" for the trial intervention (see *Appendix 2* of trial protocol for further details)

Day Month Year

Medical signature _____

INFORMATION SOURCE

<p>19. Name, profession, address and telephone number of reporter</p> <p>Reporter signature _____</p>	<p>20. Reporting date (by person reporting event)</p> <p>Day Month Year</p>
--	--

NCTU INFORMATION

<p>Date NCTU notified of SAE</p>	<p>SAE ID Code (dictated by NCTU)</p>
----------------------------------	---------------------------------------

Notes on coding ethnicity –
Please write in the box the code number from the list below that applies to the subject.

1. Caucasian
2. Black
3. Asian
4. Other

For office use only

<p style="text-align: center;">v e r i f i e d</p> <p style="text-align: center;">Date Initials</p>	<p style="text-align: center;">c o m p u t e r i s e d</p> <p style="text-align: center;">Date Initials</p>	<p style="text-align: center;">c h e c k e d</p> <p style="text-align: center;">Date Initials</p>
<p style="text-align: center;">m o n i t o r e d</p> <p style="text-align: center;">Date Initials</p>		