

REPORT OF SIGNIFICANT ADVERSE EVENT (SAE)

The Chief Investigator should report any SAE that is both related to the research procedures and is unexpected. Send the report to the Social Care Research Ethics Committee within 15 days of the CI becoming aware of the event. For further guidance see: www.screc.org.uk

1. Details of Chief Investigator

Name:	
Address:	
Telephone:	
Email:	
Fax:	

2. Details of study

Full title of study:	
Social Care REC reference number:	
Research sponsor:	
Sponsor's reference for this report: (if applicable)	

3. Type of event

Please categorise this event, ticking all appropriate options:

Death <input type="checkbox"/>	Life threatening <input type="checkbox"/>	Hospitalisation or prolongation of existing hospitalisation <input type="checkbox"/>
Persistent or significant disability or incapacity <input type="checkbox"/>	Congenital anomaly or birth defect <input type="checkbox"/>	Other <input type="checkbox"/>

4. Circumstances of event

Date of SAE:	
Location:	
Describe the circumstances of the event: <i>(Attach copy of detailed report if necessary)</i>	
What is your assessment of the implications, if any, for the safety of study participants and how will these be addressed?	

5. Declaration

Signature of Chief Investigator:	
Print name:	
Date of submission:	

6. Acknowledgement of receipt by the Social Care REC:

The Social Care Research Ethics Committee acknowledges receipt of the above.

Signed:	
Name:	
Position on REC:	
Date:	

*Signed original to be sent back to Chief Investigator (or other person submitting report)
Copy to be kept for information by the Social Care REC.*