



National Patient Safety Agency

National Research Ethics Service

REPORT OF SERIOUS ADVERSE EVENT (SAE)

(For all studies except clinical trials of investigational medicinal products)

The Chief Investigator should report any SAE that is both related to the research procedures and is unexpected. Send the report to the Research Ethics Committee that gave a favourable opinion of the research within 15 days of the CI becoming aware of the event.

1. Details of Chief Investigator

Name:	
Address:	
Telephone:	
Email:	
Fax:	

2. Details of study

Full title of study:	
Name of main REC:	
Main REC reference number:	
Research sponsor:	

Sponsor's reference for this report: (if applicable)	
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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"/>	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 main REC (please insert name):

The [] 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 main REC.*