REPORT OF SERIOUS 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 Research Ethics Committee that gave a favourable opinion of the research within 15 days of the CI becoming aware of the event. For further guidance see: *http://www.nres.npsa.nhs.uk/applicants/review/after/safety.htm.*

1. Details of Chief Investigator

Name:	Prof Willem Kuyken
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2. Details of study

Full title of study:	Preventing depressive relapse/recurrence in NHS settings through mindfulness-based cognitive therapy (MBCT)
Name of main REC:	South West Research Ethics Committee
Main REC reference number:	**09/H0206/43**
PCT number:	**(NHS Devon) 0739**
Research sponsor:	University of Exeter
Sponsor's reference for this report: (if applicable)	

3. Type of event
Please categorise this event, ticking all appropriate options:

Death ☐	Life threatening ✓	Hospitalisation or prolongation of existing hospitalization ✓
Persistent or significant disability or incapacity ☐	Congenital anomaly or birth defect ☐	Other ☐

4. Circumstances of event

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

5. Declaration

Signature of Chief Investigator:	
Print name:	Professor Willem Kuyken
Date of submission:	

6. Acknowledgement of receipt by main REC (please insert name):

The South West Research Ethics Committee 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.