THE UNIVERSITY of York

REVIEW OF SERIOUS ADVERSE EVENT/REACTION FORM

Patient's trial number: ☐☐ ☐☐☐☐

Date event reported to YTU: _____/_____/_____
Day month year

How notification of the event was made:

YTU ASSESSMENT OF THE EVENT							
Date of assessment by YTU	_____/_____/_____ day month year						
Seriousness (Please cross one box only)	Serious	☐	Non-serious	☐			
Expectedness (Please cross one box only)	Expected	☐	Unexpected	☐	Is the event listed in the reference documents, (protocol, SMPC, IB?)		
What is the relationship to the study drug? (Please cross one box only)	Not related ☐		Unlikely to be related ☐	Possibly related ☐	Probably related ☐	Definitely related ☐	Not able to assess if related ☐
Was the event a SUSAR? (Please cross one box only)	Yes	☐	No	☐			
Date SUSAR reported to MHRA	_____/_____/_____ day month year						

Date SUSAR reported to Main REC if required	_____/_____/_____ day month year					
Date and name of R&D committee SUSAR or SAE reported to, if required	Name of R&D committee _____				Date reported _____/_____/_____ day month year	
If the event was not assessed as a SUSAR, what was it assessed as?	_____					
Was the event reported to all other Principal Investigators	Yes	☐	No	☐	If yes date reported _____/_____/_____ day month year	
Action taken						
Assessment undertaken by						
Signature of reviewer(s)						
Comments						
Date reviewed by Trial Steering Committee	_____/_____/_____ day month year					
Date reviewed by Data Monitoring and Ethics Committee	_____/_____/_____ day month year					