

Stroke Oxygen Study

Eudract number: 2006-003479-11

Breach of Protocol of GCP Reporting Form

**Breach of Protocol or Good Clinical Practice reporting form****STUDY/PATIENT DETAILS**

Research Sponsor	North Staffordshire Combined Healthcare		
Main REC name:	North Staffordshire REC	Main REC reference no.	06/Q2604/109
Chief Investigator (CI):	Dr Christine Roffe	Address:	Stroke Research Office, Royal Infirmary, Prince's Road, Hartshill, Stoke-on-Trent, ST4 7LN
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EVENT DETAILS

Date Breach identified	
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Details of breach	
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Reason for breach	
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Breach of Protocol of GCP Reporting Form



Any action taken in response to breach			
Is this breach considered serious?	YES	Please email or fax to CI and Study Manager	
	Date emailed to CI and Study Manager		
	Date faxed to CI and Study Manager		
	NO	Please attach this form to the CRF	
Date attached to CRF			
Reported by		Date	
Role in study			
Contact details of person reporting incident	Tel. no.		
	Email		
Contact details: Email CI christine.roffe@northstaffs.nhs.uk Study Manager: sarah.pountain@northstaffs.nhs.uk			
Fax: 01782 555876 (office hours)			
CI USE ONLY			
Date notified of Serious Breach		Date received reporting form (RF)	
Date MHRA notified by phone		Date MHRA template form for notifications of serious breaches template form sent to MHRA	