

**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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Any action taken in response to breach			
Is this breach considered serious?	<b>YES</b>	<b>Please email or fax to CI and Study Manager</b>	
	Date emailed to CI and Study Manager		
	Date faxed to CI and Study Manager		
	<b>NO</b>	<b>Please attach this form to the CRF</b>	
Date attached to CRF			
Reported by			Date
Role in study			
Contact details of person reporting incident	Tel. no.		
	Email		
Contact details: Email CI <a href="mailto:christine.roffe@northstaffs.nhs.uk">christine.roffe@northstaffs.nhs.uk</a> Study Manager: <a href="mailto:sarah.pountain@northstaffs.nhs.uk">sarah.pountain@northstaffs.nhs.uk</a>			
Fax: 01782 555876 (office hours)			
<b>CI USE ONLY</b>			
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	