

Stroke Oxygen Study

Eudract number: 2006-003479-11

Urgent Safety Measure reporting form

**Urgent Safety Measure (USM) reporting Form**

STUDY/PATIENT DETAILS					
Research Sponsor	North Staffordshire Combined Healthcare NHS Trust				
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		
Telephone	01782 555877	Email	christine.roffe@northstaffs.nhs.uk		
Patient study number					
EVENT DETAILS					
Name of protocol					
Current version of protocol					
Date of USM		Where did the USM take place			
Describe urgent safety measures taken					
Describe reasons for urgent safety measures:					
Reported by		Date			
Role in study					
Contact details of person reporting incident	Tel. number		Email		
DATE EMAILED TO*	CI and Study Manager		Sponsor	Copy placed in Investigator Site File	
DATE FAXED TO*	CI and Study Manager		Sponsor		
Contact details: Email CI christine.roffe@northstaffs.nhs.uk Study Manager: sarah.pountain@northstaffs.nhs.uk Sponsor: nchsponsor@northstaffs.nhs.uk Fax CI and Study Manager: 01782 555876 Sponsor: 01782 441624					

***This form needs to be sent immediately to the CI, Study Manager and the Sponsor ASAP within 24 hours of the USM occurring.**

CI USE ONLY			
Date notified of USM		Date received reporting form (RF)	
Date MHRA Clinical Trials Unit notified by phone		Date main REC notified by phone	
Date substantial amendments and supporting documents sent to MHRA Clinical Trials Unit (within 3 days)		Was this faxed (020 7084 2443) or emailed (clintrialhelpline@mhra.gsi.gov.uk)	
Date substantial amendments and supporting documents sent to main REC Unit (within 3 days)		Date substantial amendments and supporting documents sent to MHRA Information Processing Unit	
Date substantial amendments and supporting documents sent to Sponsor		Date USM description sent to Study Safety Committee	