

- 8 MAR 2010



## National Research Ethics Service

### North Staffordshire Research Ethics Committee

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03 March 2010

Dr Christine Roffe  
Consultant/Reader in Geriatric Medicine  
Stroke Research Office  
North Staffordshire Combined Healthcare NHS Trust  
Holly Lodge  
62 Queens Road  
Hartshill  
Stoke-on-Trent ST4 7LH

Dear Dr Roffe

**Study title:** The Stroke Oxygen Study. A randomised controlled study of the benefits and risks of routine oxygen treatment after acute stroke

**REC reference:** 06/Q2604/109

**Protocol number:** 2

**EudraCT number:** 2006-003479-11

Thank you for notifying the Committee of the above substantial amendment to the clinical trial authorisation for this study.

It is noted that authorisation for this amendment is required from the Medicines and Healthcare products Regulatory Agency, but you have not requested an ethical opinion from the Committee.

#### Documents received

The documents received were as follows:

Document	Version	Date
GP Letter	GP letter vs 3 2nd May 2008 amendment 3 30th August 2009	30 August 2009
Flow chart	Flow chart vs 1 31 07 06 amendm 5	30 August 2009

This Research Ethics Committee is an advisory committee to West Midlands Strategic Health Authority

*The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England*

	30th Aug 2009	
Questionnaire: 12 month	SOS 3 month questionnaire amendment 1 30th Aug 2009	30 August 2009
Questionnaire: 6 month	SOS 6 month questionnaire amendment 1 30th Aug 2009	30 August 2009
Questionnaire: 3 Month	SOS 12 month questionnaire amendment 1 30th Aug 2009	30 August 2009
Participant Consent Form: After Recovery	Patient confirmation of consent (after recovery) form v4 2nd May 2008 amendment 2 30th August 2009	30 August 2009
Participant Consent Form	Patient consent form v4 2nd May 2008 amendment 2 30th August 2009	30 August 2009
Covering Letter		21 October 2009
Participant Consent Form: Relative carer of independent legal representative	Relative carer or independent legal representative consent form v4 2nd May 2008 amendment 2 30th August 2009	30 August 2009

### Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.



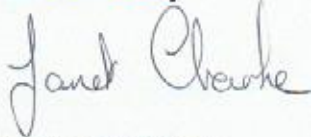
The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**06/Q2604/109:**

**Please quote this number on all correspondence**

Yours sincerely



**Mrs Janet Clarke**  
**Committee Co-ordinator**

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Copy to:

*Laurie Wrench, North Staffordshire Combined Healthcare NHS Trust*