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## North Staffordshire Local Research Ethics Committee

Mellor House  
Corporation Street  
Stafford  
Staffordshire  
ST16 3SR

Tel: 01785 257888 ext 5941

26 June 2008

Katie Roebuck  
Research Manager  
West Midlands Stroke Research Network  
Springfield Unit  
City General Hospital  
578 Newcastle Road  
Stoke-on-Trent ST4 6QG

Dear Katie

**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

**Amendment number:** 2

**Amendment date:** 02 May 2008

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 25 June 2008.

**Ethical opinion**

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

**Approved documents**

The documents reviewed and approved at the meeting were:

Document	Version	Date
Protocol	2	17 April 2008
Participant Information Sheet: Relatives and Carers	4	02 May 2008
Participant Information Sheet: Patients	4	02 May 2008
Participant Consent Form: Relative carer or independent legal representative	4	02 May 2008
Participant Consent Form	4	02 May 2008
Participant Consent Form: After Recovery	4	02 May 2008
GP/Consultant Information Sheets	3	02 May 2008
Covering Letter		30 May 2008
Annex 2 Notification of Amendment (CTIMPs)		02 May 2008

### Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

### R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

### 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.

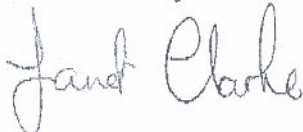
The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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



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

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Enclosures

List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to:

Dr D Clements, R&D Manager, UHNS

**North Staffordshire Local Research Ethics Committee****Attendance at Sub-Committee of the REC meeting on 25 June 2008**

<b>Present:</b>	Miss N Brooks (Chair)	Solicitor	Lay
	Prof C Cullen	Psychologist	Lay
	Mrs S Goldstraw	Nurse Member	Expert