



## National Research Ethics Service

### North Staffordshire Local Research Ethics Committee

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ST16 3SR

Tel: 01785 257888 ext 5941

29 December 2008

Dr S Pountain  
SOS Study Manager Stroke Research  
Medical Illustrations  
Royal Infirmary  
Princes Road  
Hartshill  
Stoke-on-Trent ST4 7LN

Dear Dr Pountain

**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 your letter of 29 December 2008, notifying the Committee of the above amendment.

It is noted that you do not consider this to be a substantial amendment to the clinical trial authorisation, as defined in the Medicines for Human Use (Clinical Trials) Regulations 2004, and that ethical review by the Committee is therefore not required.

#### Documents received

The documents received were as follows:

Document	Version	Date
Notification of a Minor Amendment of change of address		29/12/08

#### 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.

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

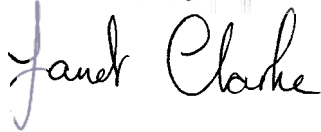
*The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England*

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:

Dr Karen Hampson, North Staffordshire Combined Healthcare NHS  
Trust, Research and Development Manager