Health Research Authority

National Research Ethics Service

NRES Committee West Midlands - Staffordshire

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11 October 2012

Dr Tracy Nevatte
SOS Study Manager
National Institute for Health Research
Stroke Oxygen Supplementation Study
North Staffs Combined Healthcare NHS Trust
Holly Lodge, 62 Queen's Road
Stoke-on-Trent
ST4 7LH

Dear Dr Nevatte

| | |
|---|---|
| **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:** | **06/Q2604/75** |
| **EudraCT number:** | **2006-003479-11** |
| **Amendment number:** | **15** |
| **Amendment date:** | **01 August 2012** |

- The amendment consists of changes to existing participant documents and inclusion of new ones

The above amendment was reviewed by the Sub-Committee in correspondence.

**Ethical opinion**

The members of the Committee taking part in the review 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 |
|---|---|---|
| Covering Letter | 1 | 30 August 2012 |
| European Commission Notification of Substantial Amendment Form | 15 | 01 August 2012 |
| Participant Consent Form | 5 | 31 July 2012 |
| Participant Consent Form: Relative, Carer or Independent Legal Representative | 5 | 31 July 2012 |
| Participant Consent Form: Independent Physician | 1 | 31 July 2012 |
| Participant Consent Form: After Recovery | 5 | 31 July 2012 |
| Discharge form | 1 | 31 July 2012 |
| Re-Admission form | 1 | 31 July 2012 |
| Case Report form | 4 | 31 July 2012 |
| Questionnaire: 3 Month Follow-up | 2 | 31 July 2012 |
| Questionnaire: 6 Month Follow-up | 2 | 31 July 2012 |
| Questionnaire: 12 Month Follow-up | 2 | 31 July 2012 |

**Membership of the Committee**

The members of the Committee who took part in the review 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 and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

Yours sincerely

Signed on behalf of:
**Dr Kathryn Kinmond**
**Chair**

E-mail: ashley.totenhofer@northwest.nhs.uk

*Enclosures:* *List of names and professions of members who took part in the review*

*Copy to:* Dr Laurie Wrench - North Staffordshire, Harplands Hospital

Professor Christine Roffe - North Staffordshire Combined Healthcare NHS Trust

**NRES Committee West Midlands - Staffordshire**

**Attendance at Sub-Committee of the REC meeting on 10 October 2012**

| *Name* | *Profession* | *Capacity* |
|---|---|---|
| Mrs Shirley Ann Goldstraw | Lecturer in Midwifery | Expert |
| Dr Kathryn Kinmond (Chair) | Senior Lecturer | Lay Plus |