

- 8 MAR 2010



National Research Ethics Service

North Staffordshire Medical Institute
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30 November 2009

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

Amendment number: 5

Amendment date: 16 October 2009

The above amendment was reviewed on 25 November 2009 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
Case record Form	SOS CRF vs 1 amend. 3 30th Aug 2009	30 August 2009
Short Protocol	Stroke Oxygen study Protocol short version	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

	vs 2 17.04.08 amendm. 5 30th Aug 2009	
Participant Information Sheet: Relative	Relative information sheet Vs 4 2 nd May 2008 amendm. 2 30th Aug 2009	30 August 2009
Participant Information Sheet: Patient	Patient information sheet Vs 4 2 nd May 2008 amendm. 3 30th Aug. 2009	30 August 2009
Protocol	Stroke Oxygen study Protocol vs 2 17.04.08 amendm. 5 30th Aug 2009	30 August 2009
European Commission Notification of Substantial Amendment Form	5	16 October 2009
Covering Letter		21 October 2009

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.

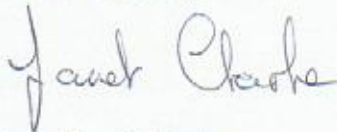
The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (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

E-mail: Janet.Clarke@uhns.nhs.uk

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

Copy to: Laurie Wrench, North Staffordshire Combined Healthcare NHS Trust

North Staffordshire Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 25 November 2009

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Miss Nicola Brooks	Solicitor	Lay
Dr Mark Gunning	Consultant Cardiologist	Expert
Dr David Hunter	Lecturer in Ethics	Lay

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