NHS
National Research Ethics Service
South East Research Ethics Committee
South East Coast Strategic Health Authority
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16 June 2009

Dr Tim England
Clinical Research Fellow to Professor Philip Bath
Nottingham University Hospitals NHS Trust
Division of Stroke Medicine
City Hospital Campus
Clinical Sciences Building
Hucknall Road
Nottingham NG5 1PB

Dear Dr England

Study title:	**Safety and tolerability of clopidogrel when added to aspirin and dipyridamole in high risk patients with recent ischaemic stroke: a randomised controlled trial**
REC reference:	**08/H1102/112**
Protocol number:	**1.1**
EudraCT number:	**2007-006749-42**
Amendment number:	**Protocol 1.2, 20/5/09**
Amendment date:	**22 May 2009**

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
Protocol	1.2	20 May 2009
Participant Information Sheet: After consent from a legal representative	1.4	03 April 2009
Participant Information Sheet: Independent Physician	1.4	03 April 2009
Participant Information Sheet: Relative	1.4	03 April 2009
Participant Information Sheet	1.4	03 April 2009
Participant Consent Form: DNA	1.4	03 April 2009
Participant Consent Form: Agreement Form (after consent from a legal representative)	1.4	03 April 2009

Participant Consent Form: Independent Physician	1.4	03 April 2009
Participant Consent Form: Relative	1.4	03 April 2009
Participant Consent Form	1.4	03 April 2009
List of changes		
Covering Letter		22 May 2009
Annex 2 Notification of Amendment (CTIMPs)	Protocol 1.2, 20/5/09	22 May 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.

08/H1102/112:	**Please quote this number on all correspondence**

Yours sincerely

Miss Nicki Watts
Committee Co-ordinator

E-mail: nicki.watts@nhs.net

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

Copy to: *Professor Philip M. W. Bath, University of Nottingham*

South East Research Ethics Committee

Members of Sub-Committee of the REC

Name	*Profession*	*Capacity*
Professor John Eastwood	Consultant Renal Physician	Expert
Dr L. Alan Ruben	GP	Expert
Mr Roy Sinclair	Pharmacist	Expert