12 JAN 2009

National Research Ethics Service
South East Research Ethics Committee
South East Coast Strategic Health Authority
Preston Hall
Aylesford
Kent
ME20 7NJ

Telephone: 01622 713097
Facsimile: 01622 885966

09 January 2009

Professor Philip M. W. Bath
Professor of Stroke Medicine
University of Nottingham
Division of Stroke Medicine,
City Hospital Campus
Nottingham
NG5 1PB

Dear Professor Bath

Full title of study:	**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 number:	**08/H1102/112**
Protocol number:	**1.1**
EudraCT number:	**2007-006749-42**

Thank you for your letter of 22 December 2008, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair's Panel.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the research site(s) taking part in this study. The favourable opinion does not therefore apply to any site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at sites requiring SSA.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Clinical trial authorisation must be obtained from the Medicines and Healthcare products Regulatory Agency (MHRA).

The sponsor is asked to provide the Committee with a copy of the notice from the MHRA, either confirming clinical trial authorisation or giving grounds for non-acceptance, as soon as this is available.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Response to Request for Further Information		21 October 2008
Peer Review		
Response to Unfavourable Opinion Letter		21 October 2008
Unfavourable Opinion Letter		14 October 2008
MHRA Notice of Acceptance		17 October 2008
Evidence of Insurance		05 August 2008
Request form for authorisation from the MHRA		12 August 2008
GP/Consultant Information Sheets	1.1	17 October 2008
Letter from Sponsor		22 August 2008
Protocol	1.1	17 October 2008
Investigator CV	Professor Philip Bath	13 August 2008
Application		21 October 2008
Questionnaire: Mood Questionnaire (Zung Depression Scale)		
Questionnaire: Quality of Life Questionnaire (EuroQol)		
Response to Request for Further Information		22 December 2008
Participant Consent Form: DNA Testing	1.3	22 December 2008
Participant Consent Form: Independent Physician	1.3	22 December 2008
Participant Consent Form: For patients with consent by relative or legal representative	1.3	22 December 2008
Participant Consent Form: Relative	1.3	22 December 2008
Participant Consent Form	1.3	22 December 2008
Participant Information Sheet: Independent Physician	1.3	22 December 2008
Participant Information Sheet: For patients with consent by relative or legal representative	1.3	22 December 2008
Participant Information Sheet: Relative	1.3	22 December 2008
Participant Information Sheet	1.3	22 December 2008

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.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review –guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

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

With the Committee's best wishes for the success of this project

Yours sincerely

pp **Dr L. Alan Ruben**
Chair

Email: nicki.watts@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Mr Paul Cartledge*
Clinical Trials Unit, MHRA