

MB → MA



# National Research Ethics Service

05 JUL 2010

## South East Research Ethics Committee

South East Coast Strategic Health Authority  
Preston Hall  
Aylesford  
Kent  
ME20 7NJ

Tel: 01622 713048  
Fax: 01622 885966

24 June 2010

Professor Philip M. W. Bath  
Professor of Stroke Medicine  
University of Nottingham  
Division of Stroke Medicine - Research Dept  
Clinical Sciences Building  
City Hospital Campus  
Hucknall Road  
Nottingham  
NG5 1PB

Dear Professor Bath

<b>Study title:</b>	<b>Safety and tolerability of clopidogrel when added to aspirin and dipyridamole in high risk patients with recent ischaemic stroke: a randomised controlled trial</b>
<b>REC reference:</b>	<b>08/H1102/112</b>
<b>Protocol number:</b>	<b>31350</b>
<b>EudraCT number:</b>	<b>2007-006749-42</b>
<b>Amendment number:</b>	<b>90 Day follow up</b>
<b>Amendment date:</b>	<b>03 June 2010</b>

Thank you for your letter of 03 June 2010, 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
GP letter		
Notification of a Minor Amendment		03 June 2010

**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

**Mr Dean Beattie**  
**Committee Co-ordinator**

E-mail: dean.beattie@nhs.net

*Copy to:*

*Mr Paul Cartledge*  
*Margaret Adrian, TARDIS Trial Nurse Coordinator*