

**NRES Committee London - South East**

Bristol Research Ethics Committee Centre  
Level 3, Block B  
Whitefriars,  
Lewins Mead,  
Bristol  
BS1 2NT

Telephone: 0117 342 1382  
Facsimile: 0117 342 0445

06 March 2013

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

**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:** 31350

**EudraCT number:** 2007-006749-42

**Amendment number:** 13

**Amendment date:** 21 December 2012

**IRAS project ID:**

Thank you for submitting the above amendment, which was received on 22 January 2013.

| Research Site                             | Principal Investigator / Local Collaborator |
|-------------------------------------------|---------------------------------------------|
| County Durham & Darlington NHS Foundation | Bernard Esisi                               |
| Buckinghamshire Healthcare Trust          | Matthew Burn                                |
| Heart of England NHS Foundation Trust     | Ibrahim Memon                               |
| South Tees Hospitals                      | David Broughton                             |
| Wirral University                         | Ruth Davies                                 |
| Peterborough and Stamford Hospitals       | Peter Owusu-Ahyei                           |
| Epsom & St Helier University              | Janet Putterill                             |
| University College Halton                 | Richard Perry                               |
| Warrington and Halton                     | Karim Mahawish                              |
| North Tees and Hartlepool                 | David Bruce                                 |
| South London Healthcare NHS Trust         | Bartlomiej Piechowski-Jozwiak               |
| The Royall Free Hampstead                 | Charlie Davie                               |
| Norfolk and Norwich University            | Kneale Metcalfe                             |

|                                                                                      |                   |
|--------------------------------------------------------------------------------------|-------------------|
| The Queen Elizabeth Hospital King's Lynn<br>NHS Trust Grayton                        | Raj Shekhar       |
| Plymouth Hospitals NHS Trust Derriford<br>Road                                       | Azlisham Mohd Nor |
| Hampshire Hospitals NHS Foundation Trust<br>Basingstoke and North Hampshire Hospital | Elio Giallombardo |
| Weston Area Health NHS Trust Weston<br>General Hospital                              | Harbans Bhakri    |
| West Suffolk Hospital NHS Trust                                                      | Abul Azim         |
| Ashford and St Peters NHS Foundation Trust                                           | Peter Wilkinson   |
| Calderdale and Huddersfield NHS<br>Foundation Trust                                  | Anand Nair        |
| University Hospitals Bristol Foundation Trust                                        | Peter Murphy      |
| Derby Hospitals NHS Foundation Trust                                                 | Timothy England   |

The amendment relates solely to the addition of new site(s) and/or investigator(s) within the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland. The site-specific assessment for the site(s) will therefore form part of the research governance review. The Site-Specific Information (SSI) Form for the site should be included with the application for R&D approval.

On behalf of the Committee, I am pleased to confirm the extension of the favourable opinion to the new site(s) and/or investigator(s), subject to management permission being given by the relevant NHS/HSC R&D office(s) prior to the study starting at the site.

### 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.

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| <b>08/H1102/112</b> | <b>Please quote this number on all correspondence</b> |
|---------------------|-------------------------------------------------------|

Yours sincerely



**Mr Tom Fairman**  
**Committee Co-ordinator**

Email: [nrescommittee.london-southeast@nhs.net](mailto:nrescommittee.london-southeast@nhs.net)

Copy to: *Mr Paul Cartledge*