



# Health Research Authority

## NRES Committee London - South East

Bristol Research Ethics Committee Centre  
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21 May 2013

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:** Substantial Amendment Addition of sites/PI dated 27 Feb 2013 SA01/13

**Amendment date:** 27 February 2013

**IRAS project ID:**

Thank you for submitting the above amendment, which was received on 25 April 2013.

Research Site	Principal Investigator / Local Collaborator
Burton Hospital NHS Trust, Queens Hospital, Belvadere Road	Partha Das
Airedale NHS Foundation Trust, Ward 5, Stroke Unit, Airedale General Hospital, Steeton, Keighly, W Yorks BD20 6TD	Matthew Smith
Mid Staffordshire NHS Foundation Trust, Cannock Chase Hospital/Stafford Hospital WS11 5XY/ST16 3SA	Anthony Oke
The Macclesfield District General Hospital, Victoria Road, Macclesfield, Cheshire SK10 3BL	Moe Sein
The Royal Albert Edward Infirmary, Wrightington, Wigan & Leigh NHS Foundation Trust	Sunil Herath
F15, University of South Manchester NHS Foundation Trust, Wythenshaw Hospital	Ed Gamble
Wye Valley NHS Trust, The County Hospital, Union Walk, Hereford HR1 2ER	Colin Jenkins
Pennine Acute Hospital NHS Trust, Fairfield General Hospital, Rochdale Road, Bury, Greater Manchester BL9 7TD	Robert Namushi
Basildon University Hospital, Nether mayne,	Ravi Rangasamy – Change of

Basildon, Essex SS16 5NL	coordinating investigator from previous coordinating investigator (Dr Udayaraj Umasankar) noted
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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.

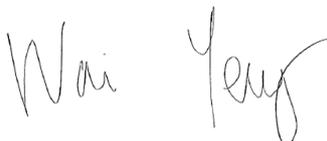
The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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.

**08/H1102/112**

**Please quote this number on all correspondence**

Yours sincerely



**Mr Wai Yeung**  
**Assistant Committee Co-ordinator**

Email: nrescommittee.london-southeast@nhs.net

Copy to: *University of Nottingham*