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09 NOV 2010

National Research Ethics Service

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

Telephone:
Facsimile:

05 November 2010

Mrs Margaret Adrian
TARDIS Trial – Nurse Co-ordinator
University of Nottingham
Division of Stroke Medicine
Clinical Sciences Building
Nottingham University Hospitals NHS Trust
Hucknall Road
Nottingham
NG5 1PB

Dear Mrs Adrian

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 number:	**08/H1102/112**
Protocol number:	**31350**
EudraCT number:	**2007-006749-42**
Amendment number:	**SA05/10 7 October 2010**
Amendment date:	**08 October 2010**

Thank you for submitting the above amendment, which was received on 11 October 2010.

Research Site	Principal Investigator / Local Collaborator
Croydon Health Services NHS Trust, Croydon University Hospital, 530 London Road, Croydon, London CR7 7YE	Lawrence Enas
Royal Surrey County Hospital, Egerton Road, Guilford, Surrey, GU2 7XX	Adrian Blight

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 (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

Sophie Vella
Assistant Co-ordinator

Email:

Copy to: Professor Philip M. W. Bath