



Health Research Authority

NRES Committee London - South East

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

Tel: (0117) 3421382

22 April 2014 – Re-issued 29 May 2014

Mr Paul Cartledge
Research Innovation Services, University of Nottingham
Kings Meadow Campus, Lenton Lane
Nottingham NG7 2NR

Dear Mr Cartledge

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: Email received

Amendment date: 10 March 2014

Thank you for your letter of 10 March 2014, 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
Notification of a Minor Amendment	Email received	10 March 2014
GP/Consultant Information Sheets (TARDIS letter to GP at baseline (clean & tracked)	1.3a	23 January 2014

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the

A Research Ethics Committee established by the Health Research Authority

Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

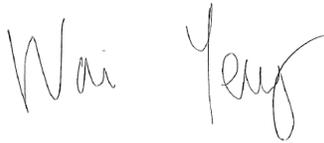
The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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

A handwritten signature in black ink that reads "Wai Yeung". The signature is written in a cursive, flowing style.

Mr Wai Yeung
Research Ethics Committee (REC) Assistant

E-mail: nrescommittee.london-southeast@nhs.net

Copy to: *Professor Philip M. W. Bath, University of Nottingham*