NHS Health Research Authority NRES Committee East of England - Hertfordshire

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21 June 2012

Professor Alison Halliday

alison.halliday@nds.ox.ac.uk Consultant Vascular Surgeon & Reader Asymptomatic Carotid Surgery Trial-2 (ACST-2) Nuffield Department of Surgical Sciences Level 6 John Radcliffe Hospital Headington Oxford OX3 9DU

Dear Professor Halliday

Study title:

REC reference: Amendment number: Amendment date: Amendment details: ACST -2: Asymptomatic Carotid Surgery Trial-2: surgery vs stenting 05/Q0201/66 Amendment #7 (Minor) 14 June 2012 Payment of £100 to the collaborating institution for each participant in the trial as a contribution to each institution towards the costs of additional time taken by researchers in explaining and discussing the trial with each potential participant and with the work involved in completing the paperwork. Sponsor has confirmed that this amendment is not a substantial amendment.

Thank you for your letter of 14 June 2012, notifying the Committee of the above amendment.

We note that your sponsor does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	Version	Date
	Amendment #7 Minor Letter from Trial Coordinator re payments to collaborating institutions.	14 June 2012
	Email from Carol Cornelius, Clinical Trials & Research Governance, University of Oxford	21 June 2012

Statement of compliance

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.

05/Q0201/66: Please quote this number on all correspondence

Yours sincerely

Har Han Karw.

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