NHS
National Research Ethics Service
NRES Committee East of England - Hertfordshire

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14 September 2011

Professor Alison Halliday
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:	**ACST-2: Asymptomatic Carotid Surgery Trial-2: surgery vs stenting**
REC reference:	**05/Q0201/66**
Amendment number:	**Amendment #6 (Minor)**
Amendment date:	**13 September 2011**

Thank you for the letter of 13 September 2011, from Tricia Carver, notifying the Committee of the above amendment.

The Committee 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
Notification of a Minor Amendment - Email from Tricia Carver, Trial Manager		13 September 2011
GP/Consultant Information Sheets	2	13 September 2011

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for

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

Yours sincerely

Miss Anna Bradnam

E-mail: Anna.Bradnam@eoe.nhs.uk

Cc: *Mrs H House,*
Head of Clinical trials and Research Governance
Manor House
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Headington, Oxford
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Tricia Carver, Trial Manager
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[redacted]

Re: _____

DOB_____

Dear Dr

Asymptomatic Carotid Surgery Trial-2 (ACST-2): an international randomised trial to compare carotid endarterectomy with carotid artery stenting to prevent stroke.

Your patient _____ has consented to participate in the above multinational, multicentre trial of 5000 patients.

The Primary objectives of the study are to compare:
1) peri-procedural risks myocardial infarction (MI), stroke and death within the first month after the allocated CEA or CAS.
2) long-term (up to 5 or more years) prevention of stroke, particularly disabling or fatal stroke, in subsequent years.

Patients will be randomized on a 1:1 ratio to either CEA or CAS.

Successful treatment of carotid narrowing will reduce the chance of the patient having a stroke from it in the future, but CEA and CAS themselves carry a relatively small risk of causing an immediate stroke or heart attack.

Patients in this study will be advised to contact their study doctor immediately if they are unable to attend scheduled clinic visits, experience illness or discomfort.

If you are concerned at any time or require additional information regarding this trial, please contact Prof Alison Halliday on 01865 221 290.

Yours sincerely,

Prof Alison Halliday
Consultant Vascular Surgeon