Hertfordshire 1 Research Ethics Committee
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11 October 2005

Miss Alison Halliday
Consultant Vascular Surgeon & Reader
St George's University of London
ACST Office, Department of Cardiological Sciences
St George's University of London
Cranmer Terrace, London
SW17 ORE

Dear Miss Halliday

Full title of study: **ACST -2: Asymptomatic Carotid Surgery Trial-2: surgery vs stenting**

REC reference number: **05/Q0201/66**

The Research Ethics Committee reviewed the above application at the meeting held on 12 September 2005.

Ethical opinion

Record of ethical issues discussed including important clarifications or assurances given by the applicant.

The Committee would like the Participant Information sheet the participant's GP will be informed with their consent.
The Committee would also like the 'Disadvantages' paragraph on the Participant Information Sheet rewritten to better portray a balanced of the advantages and disadvantages and put the disadvantages in context. The Committee advised that

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation.

Ethical review of research sites

[Extra paragraph for use by Administrators where the study as a whole is not exempt but the main REC decides to exempt an individual site from SSA. The paragraph may also be used during the progress of the study where the Chief Investigator seeks exemption from SSA for a new site. Note that in the case of a CTIMP, a PI must be named for the site even where SSA is not required.
The Committee has agreed that site-specific assessment is not required for the following site(s):

Research site	*Name of PI (CTIMPs only) or local contact point*	*Post*

	Miss Alison Halliday	
St George's University of London		

The favourable opinion for the study therefore applies to the above site(s). There is no need to complete Part C of the application form or to inform Local Research Ethics Committees (LRECs) about the research. However, all researchers and local research collaborators who intend to participate in this study at NHS sites should notify the R&D Department for the relevant care organisation and seek research governance approval.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Application		17 August 2005
Investigator CV		
Protocol	1.3	17 August 2005
Covering Letter		17 August 2005
Letter from Sponsor		29 July 2005
Participant Information Sheet	3.1	01 July 2005
Participant Consent Form	2.1	01 July 2005

Research governance approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final research governance approval from the R&D Department for the relevant NHS care organisation.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

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.

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

With the Committee's best wishes for the success of this project

Yours sincerely

pp JWinter

Mrs Bridget Vickers

05/Q0201/66

Chair

Email: andreas.marcou@bhsha.nhs.uk

Enclosures:	*List of names and professions of members who were present at the meeting and those who submitted written comments* *Standard approval conditions [SL-AC1 for CTIMPs, SL-AC2 for other studies]* *Site approval form (SF1)*
Copy to:	*Mary Anne Tourette* *St Georges University of London* *Cranmer Terrace* *London* *SW17 0RE* *R&D Department*

Hertfordshire 1 Research Ethics Committee

LIST OF SITES WITH A FAVOURABLE ETHICAL OPINION

For all studies requiring site-specific assessment, this form is issued by the main REC to the Chief Investigator and sponsor with the favourable opinion letter and following subsequent notifications from site assessors. For issue 2 onwards, all sites with a favourable opinion are listed, adding the new sites approved.

REC reference number:	05/Q0201/66	**Issue number:**	1	**Date of issue:**	11 October 2005
Chief Investigator:	Miss Alison Halliday				
Full title of study:	ACST -2: Asymptomatic Carotid Surgery Trial-2: surgery vs stenting				

This study was given a favourable ethical opinion by Hertfordshire 1 Research Ethics Committee on 12 September 2005. The favourable opinion is extended to each of the sites listed below. The research may commence at each NHS site when management approval from the relevant NHS care organisation has been confirmed.

Principal Investigator	*Post*	*Research site*	*Site assessor*	*Date of favourable opinion for this site*	*Notes* (1)

Approved by the Chair on behalf of the REC:

J Winter ..... *(Signature of ~~Chair~~/Administrator)*

(delete as applicable)

J WINTER ..... (Name)

(1) *The notes column may be used by the main REC to record the early closure or withdrawal of a site (where notified by the Chief Investigator or sponsor), the suspension of termination of the favourable opinion for an individual site, or any other relevant development. The date should be recorded.*