

NOTICE OF SUBSTANTIAL AMENDMENT (non-CTIMP)

For use in the case of all research other than clinical trials of investigational medicinal products (CTIMPs). For substantial amendments to CTIMPs, please use the EU-approved notice of amendment form (Annex 2 to ENTR/CT1) available in the Integrated Research Application System (IRAS) at <http://www.myresearchproject.org.uk> or on the EudraCT website at <https://eudract.ema.europa.eu/document.html>.

To be completed in typescript by the Chief Investigator in language comprehensible to a lay person and submitted to the Research Ethics Committee that gave a favourable opinion of the research ("the main REC"). In the case of multi-site studies, there is no need to send copies to other RECs unless specifically required by the main REC.

Further guidance is available at <http://www.nres.nhs.uk/applications/after-ethical-review/notification-of-amendments/>.

Details of Chief Investigator:	
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Full title of study:	Asymptomatic Carotid Surgery Trial (ACST-2): an international randomised trial to compare Carotid Endarterectomy with Carotid Artery Stenting to prevent stroke.
Lead sponsor:	HTA
Name of REC:	Hertfordshire 1 Research Ethics Committee
REC reference number:	05/Q0201/66
Name of lead R&D office:	ORH NHS Trust

Date study commenced:	01/04/2007
Protocol reference (if applicable), current version and date:	
Amendment number and date:	Amendment 8 8 October 202

Type of amendment (indicate all that apply in bold)

(a) *Amendment to information previously given on the REC Application Form*

Yes No

If yes, please refer to relevant sections of the REC application in the "summary of changes" below.

(b) *Amendment to the protocol*

Yes No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

(c) *Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study*

Yes No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified to the REC and given an unfavourable opinion?

Yes No

Summary of changes

Briefly summarise the main changes proposed in this amendment using language comprehensible to a lay person. Explain the purpose of the changes and their significance for the study.

If this is a modified amendment, please explain how the modifications address concerns raised previously by the ethics committee.

If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

Use of a different medium to advertise the trial for patients – to be used in clinics and hospital vascular laboratories

Any other relevant information

Applicants may indicate any specific ethical issues relating to the amendment, on which the opinion of the REC is sought.

List of enclosed documents

Document	Version	Date
Clinic poster	1	1 October 2012

List of enclosed documents

Document	Version	Date

Declaration by Chief Investigator

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment to be implemented.

Signature of Chief Investigator: 

Print name: ALISON HAYWARD

Date of submission: 8/10/12

Declaration by the sponsor's representative

The sponsor of an approved study is responsible for all amendments made during its conduct.

The person authorising the declaration should be authorised to do so. There is no requirement for a particular level of seniority; the sponsor's rules about delegated authority should be adhered to.

- I confirm the sponsor's support for this substantial amendment.

Signature of sponsor's representative: 

Print name: C. L. CORNELIUS

Post: SENIOR RESEARCH SUPPORT ASSOCIATE

Organisation: UNIVERSITY OF OXFORD

Date: 22/10/12