National Research Ethics Service

NHS Health Research Authority

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*