National Patient Safety Agency

National Research Ethics Service

NOTICE OF SUBSTANTIAL AMENDMENT

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) at http://eudract.emea.eu.int/document.html#guidance.

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.npsa.nhs.uk/applicants/review/after/amendments.htm.

Details of Chief Investigator:

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Full title of study:	Prevention Of Decline in Cognition After Stroke Trial (PODCAST): A factorial randomised controlled trial of intensive versus guideline lowering of blood pressure and lipids
Name of main REC:	Nottingham Research Ethics Committee 1
REC reference number:	09/H0403/71
Date study commenced:	September 2010
Protocol reference *(if applicable)*, current version and date:	09012, Version 1.4, April 2011

Amendment number and date:	Amendment 5

Type of amendment (indicate all that apply in bold)

(a) Amendment to information previously given on the NRES 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. In the case of a modified amendment, highlight the modifications that have been made.

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.

1. To simplify trial procedures, we will ask the same blood tests (lipids and UEs) for all participants, irrespective of the trial arm, for the clinic follow-up visits. A fasting glucose has now been added to the above.
2. The ECG from the index event will be collected at the first clinic appointment. An ECG will be taken at each clinic follow-up visit.

3. The ambulatory blood pressure monitoring, as part of the sub-study, will now be performed at all scheduled, follow-up clinic appointments. (Previously only at Baseline, 6 month and 18 month clinic visits).
4. The updated protocol clarifies that the GP does not need to be GCP trained as they will not be involved in screening and recruiting patients.

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*
Podcast protocol: Summary of changes		26 April 2011
Protocol (final version with tracked changes)	1.4	26 April 2011
Participant Information Sheet: Main Study	1.4	26 April 2011
Participant Information Sheet: Sub Studies	1.4	26 April 2011
Participant Consent Form: Sub Studies	1.4	26 April 2011
Participant Consent Form: Screening	1.4	26 April 2011
Participant Consent Form: Main	1.4	26 April 2011
GP Practice Briefing Letter	1.4	26 April 2011
GP Letter: Enrolment	1.4	26 April 2011
GP Letter: Patient develops dementia	1.4	26 April 2011

Declaration

- 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: Professor Philip Bath

Date of submission: 4th May, 2011