NHS
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 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 1.2, 22 July 2010
Amendment number and date:	01, 22 July 2010

Type of amendment (indicate all that apply in bold)

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

No

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

(b) Amendment to the protocol

Yes. Updated protocol with highlighted changes and summary of changes attached.

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. Revised forms with highlighted changes and summary of changes attached.

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. The updated protocol clarifies that the treatment algorithms are only a guide and specific drugs for individual patients should be guided by local policy and practice. To this effect, the algorithms for guideline BP and lipid management have been withdrawn. This section of the protocol has been revised and updated
2. Informed consent: Following feedback from the Scottish REC and recruiting sites, it was felt that as all participants have consented to participate in the study, re-consenting by an informant, should participants lose capacity, was not felt necessary. However, as per the Mental Capacity Act 2005,

England, if the participants lost capacity during the trial and the informant felt it was not in the participant's best interests, they may choose to withdraw them from the study. The informant sheets/consent forms related to participants losing capacity have been withdrawn.

3. GP involvement: The protocol clarifies and updates trial related procedures involving GPs such as recruitment, GP investigations and follow-up. They will also be provided with more information regarding the study at the time of screening and relevant Quality and Outcome Framework (QOF) indicators collected during the trial will be fed back to the GPs. A GP practice briefing sheet, which details GP involvement in the trial, will now be sent at the time of participant screening to the GPs.
4. Scan transfer and storage: This section has been updated to be compliant with the Data Protection Act and the NHS guidelines regarding transfer of electronic data.

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*
1. Podcast Protocol: Summary of changes.		22 July 2010
2. Protocol with (final version and with tracked changes)	Version 1.2	22 July 2010
3. Participant Information Sheet: Main Study	Version 1.2	22 July 2010
4. Participant Information Sheet: Sub Studies	Version 1.2	22 July 2010
5. Participant Consent Form: Screening	Version 1.2	22 July 2010
6. Participant Consent Form: Main Study	Version 1.2	22 July 2010
7. Participant Consent Form: Sub Studies	Version 1.1	22 July 2010
8. Informant Information Sheet	Version 1.1	22 July 2010
9. Informant Consent Form	Version 1.1	22 July 2010
10. GP Letter: Screening	Version 1.1	22 July 2010
11. GP Letter: Recruitment	Version 1.2	22 July 2010
12. GP Letter: Diagnosis of Probable Dementia	Version 1.1	22 July 2010
13. GP Letter: Practice Briefing Sheet	Version 1.0	22 July 2010

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: P BAZA

Date of submission: 9/8/10