NHS
National Research Ethics Service

NRES Committee East Midlands - Nottingham 1
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19 May 2011

Professor Phillip Bath
Professor of Stroke Medicine
Division of Stroke Medicine
Clinical Sciences Building
Nottingham City Hospital
Hucknall Road
Nottingham NG5 1PB

Dear Professor Bath

Study title:	**Prevention Of Decline in Cognition After Stroke Trial(PODCAST):A factorial randomised controlled trial of intensity versus guideline lowering of blood pressure and lipids**
REC reference:	**09/H0403/71**
Protocol number:	**1.4**
Amendment number:	**5**
Amendment date:	**04 May 2011**

The above amendment was reviewed at the meeting of the Sub-Committee held on 10 May 2011.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Participant Consent Form: Screening	1.4	26 April 2011
Participant Consent Form: Sub-Studies	1.4	26 April 2011
Participant Information Sheet: Sub-Studies	1.4	26 April 2011
Participant Information Sheet: Main Study	1.4	26 April 2011
Protocol	1.4	26 April 2011
Notice of Substantial Amendment (non-CTIMPs) - 1. To simplify trial procedures, the same blood tests (lipids and UEs) will be taken for all participants, irrespective of the trial arm, for the clinic follow-up visits. A fasting glucose has now been added to the above.		04 May 2011

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.		
Covering Letter		26 April 2011
GP Letter: Diagnosis of Probable Dementia	1.4	26 April 2011
GP Letter: Enrolment	1.4	26 April 2011
protocol Amendment - Summary of Changes 1.2 - 1.4		
GP/Consultant Information Sheets	GP Letter/Practice Brlefing Sheet	26 April 2011
Participant Consent Form: Main Study	1.4	26 April 2011

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

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.

09/H0403/71:	**Please quote this number on all correspondence**

Yours sincerely

P. Wheat

pp **Mr Robert Johnson**
Chair

E-mail: trish.wheat@nottspct.nhs.uk

Enclosures: *List of names and professions of members who took part in the review*

Copy to: Mr Paul Cartledge - University of Nottingham

R&D office for NHS care organisation at lead site - NUH

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Attendance at Sub-Committee of the REC meeting on 10 May 2011

Name	*Profession*	*Capacity*
Mr Robert Johnson	Research Coordinator	Expert
Reverend Keith Lackenby	Lay member	Lay

Also in attendance:

Name	*Position (or reason for attending)*
Ms Trish Wheat	REC Committee Co-ordinator