

National Research Ethics Service

Nottingham Research Ethics Committee 1

24 SEP 2010

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14 September 2010

Professor Philip Bath
Professor of Stroke Medicine
University of Nottingham
Professor of Stroke Medicine
Division of Stroke Medicine
CSB, City Hospital
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: 09012
Amendment number: 2
Amendment date: 09 August 2010

The above amendment was reviewed at the meeting of the Sub-Committee held on 14 September 2010.

Ethical opinion

Favourable 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
Podcast Protocol: Summary of changes		
Notice of Substantial Amendment (non-CTIMPs)	2	09 August 2010
Participant Consent Form: Informant consent form	1.1	22 July 2010
Participant Information Sheet: Participant Consent form - Main Study	1.2	22 July 2010
GP Letter - Practice briefing sheet	1.0	22 July 2010
Participant Consent Form: Participant consent form - Sub studies	1.1	22 July 2010

Participant Consent Form: Participant consent form - screening	1.2	22 July 2010
GP letter - Recruitment	1.2	22 July 2010
GP letter - screening	1.1	22 July 2010
GP letter - diagnosis of probable dementia	1.1	22 July 2010
Participant Information Sheet: Informant information sheet	1.1	22 July 2010
Participant Information Sheet: - Sub Studies	1.2	22 July 2010
Participant Information Sheet: - Main Study	1.2	22 July 2010
Protocol	1.2	22 July 2010

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



Ms Trish Wheat
Committee Co-ordinator

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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 14 September 2010

Committee Members:

Name	Profession	Present	Notes
Mr Robert Johnson	Research Coordinator	Yes	
Rev Keith Lackenby	Lay member	Yes	

Also in attendance:

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