



## Health Research Authority

### NRES Committee East Midlands - Nottingham 1

The Old Chapel  
Royal Standard Place  
Nottingham  
NG1 6FS

Tel: 0115 883 9390

13 August 2013

Professor Philip Bath  
University of Nottingham  
Division of Stroke Medicine  
CSB, City Hospital  
Nottingham  
NG5 1PB

Dear Professor Bath,

<b>Study title:</b>	<b>Prevention Of Decline in Cognition After Stroke Trial(PODCAST):A factorial randomised controlled trial of intensity versus guideline lowering of blood pressure and lipids.</b>
<b>REC reference:</b>	<b>09/H0403/71</b>
<b>Protocol number:</b>	<b>09012</b>
<b>Amendment number:</b>	<b>6 - 25/06/2013</b>
<b>Amendment date:</b>	<b>16 July 2013</b>
<b>IRAS project ID:</b>	<b>18461</b>

The above amendment was reviewed at the meeting of the Sub-Committee held on 13 August 2013.

#### **Ethical opinion**

There were no Ethical issues

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 Information Sheet: Participant Information Sheet - Main Study	1.6 (Clean & Tracked)	15 April 2013
Protocol	1.6 (Clean & Tracked)	11 April 2013
Participant Information Sheet: Informant Information Sheet	1.2 (Clean & Tracked)	16 April 2013
GP/Consultant Information Sheets	1.0 (Clean & Tracked)	15 April 2013
Covering Letter	From Professor Bath	16 July 2013
Participant Information Sheet: participant Information Sheet - Sub Studies	1.5 (Clean & Tracked)	19 March 2013
Summary of Changes		25 June 2013
Notice of Substantial Amendment (non-CTIMPs)	6 - 25/06/2013	16 July 2013

## 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.

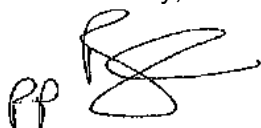
## Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

<b>09/H0403/71:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely,



**Reverend Keith Lackenby**  
**Vice Chair**

E-mail: NRESCCommittee.EastMidlands-Nottingham1@nhs.net

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

*Copy to: Dr Maria Koufali, Nottingham University Hospital NHS Trust*  
*Paul Cartledge*

**NRES Committee East Midlands - Nottingham 1**

**Attendance at Sub-Committee of the REC meeting on 13 August 2013**

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Reverend Keith Lackenby	Lay member	Lay Plus
Mr Jon Merrills	Barrister / Pharmacist	Expert

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Rebecca Morledge	Assistant Coordinator