

**NRES Committee East Midlands - Nottingham 1**

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13 June 2012

Professor Philip Bath  
Professor of Stroke Medicine  
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>Amendment 7 (Substantial Amendment 4) 28 February 2012</b>
<b>Amendment date:</b>	<b>15 May 2012</b>

The above amendment was reviewed at the meeting of the Sub-Committee held on 12 June 2012.

**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
Notice of Substantial Amendment (non-CTIMPs)	Amendment 7 (Substantial Amendment 4) 28 February 2012	15 May 2012
Covering Letter		04 April 2012
Podcast study Substantial protocol Amendment Summary of changes	1.4 to 1.5	
Protocol	1.5 28 February 2012	28 February 2012
Participant Consent Form: Main Study	1.5	28 February 2012
Participant Information Sheet: Main Study	1.5	28 February 2012

Participant Consent Form: Screening	1.5	28 February 2012
GP Letter: Enrolment	1.5	28 February 2012
GP Letter: Screening	1.5	28 February 2012
GP Letter: Practice Briefing Sheet	1.6	28 February 2012

### 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.

09/H0403/71:

Please quote this number on all correspondence

Yours sincerely

*pp: W Rees*

**Mr Robert Johnson**  
Chair

E-mail: Wendy.Rees@nottspct.nhs.uk

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 head of research, grants and contracts., University of Nottingham*

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**Attendance at Sub-Committee of the REC meeting on 12 June 2012**

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Mr Robert Johnson	Expert member	Expert
Reverend Keith Lackenby	Lay member	Lay Plus

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Andrea Graham	REC Coordinator
Wendy Rees	Assistant Coordinator