18 NOV 2009

NHS

National Research Ethics Service

Nottingham Research Ethics Committee 1
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12 November 2009

Professor Philip Bath
Professor of Stroke Medicine
University of Nottingham
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 number:	**09/H0403/71**
Protocol number:	**1.1**

Thank you for your letter of 13 October 2009, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Mental Capacity Act 2005

I confirm that the committee has approved this research project for the purposes of the Mental Capacity Act 2005. The committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk. *Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.*

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Response to Request for Further Information		13 October 2009
Protocol	1.1	12 October 2009
Investigator CV	Student	
Participant Information Sheet: Main Study	1.0	12 October 2009
Participant Information Sheet: Main Study Informant - if participant loses capacity to maintain consent	1.1	12 October 2009
Participant Consent Form: Main Study - Screening	1.1	12 October 2009
Participant Consent Form: Main Study	1.1	12 October 2009
Participant Consent Form: Main Study Informant - if participant loses capacity to maintain consent	1.1	12 October 2009
GP/Consultant Information Sheets	1.1	12 October 2009
Evidence of insurance or indemnity		28 July 2010
Referees or other scientific critique report	Stroke Association	
GP Letter - Re: patient developing probable dementia	1.0	12 October 2009
Letter from Alzheimer's Society regarding lay reviewers		01 October 2009
Letter from Scotland A REC		28 September 2009
Investigator CV		
REC application	18461/51865/1/950	24 July 2009
Participant Information Sheet: Relative (if participant loses capacity to maintain consent)	1.0	24 July 2009

Evidence of Insurance		05 August 2008
Letter from Sponsor		24 July 2009
Letter from Funder: The Alzheimer's Society		05 February 2008
Letter from Funder: The Stroke Association		29 January 2009

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.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

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

Yours sincerely

pp Johnson

Mr Robert Johnson
Vice Chair

Email: trish.wheat@nottspct.nhs.uk

Enclosures: "After ethical review – guidance for researchers" *SL- AR2 for other studies*

Copy to: *Mr Paul Cartledge*
R&D office for NHS care organisation at lead site – NUH (via email)