



The University of
Nottingham

UNITED KINGDOM • CHINA • MALAYSIA

Mr Robert Johnson
Chair
NRES Committee East Midlands – Nottingham 1
Health Research Authority Research Ethics Committee (REC) Centre
The Old Chapel,
Royal Standard Place,
Nottingham,
NG1 6FS

School of Clinical Science
Division of Stroke

Clinical Sciences Building
City Hospital Campus
Hucknall Road
Nottingham
NG5 1PB

t: +44 (0)115 823 1761
f: +44 (0)115 823 1761

www.nottingham.ac.uk/scs/divisions/stroke

Head of Department
Professor P M W Bath

16th July 2013

Dear Mr Johnson,

Study Title: **Prevention of Decline in Cognition After Stroke Trial (PODCAST): A factorial randomised trial of Intensive versus guideline lowering of blood pressure and lipids.**

REC reference: **09/H0403/71**

This clinical trial received a favourable opinion letter on 12th November 2009 and we commenced recruitment in September 2010.

I am writing regarding substantial amendment 6 to the PODCAST trial. The updated version 1.6 of the protocol consists primarily of the following changes in the running of the trial:

1. The aim of the trial is to recruit up to 120 participants by the end of January 2014 as the trial is not progressing to the main phase.
2. The duration of the trial has been reduced from 8 years to 4 years, with follow up ending at the end of August 2014.
3. We plan to collect additional information from any CT/MRI scan of the brain if performed for clinical reasons during the trial period.
4. The previous versions of the protocol already mention that GP's will be updated on patient progress annually following recruitment, please see enclosed the letter the patients GP will receive, after the participant has been in the trial for 1 year.

The updated documents with tracked changes are enclosed.
We request that you kindly review and approve these changes to the conduct of the trial.

Enclosures:

1. Summary of changes 25 June 2013
2. Protocol Version 1.6 dated 15 April 2013 (with tracked changes and updated document)
3. Participant Information Sheet: Main Study, version 1.6, 16 April 2013
4. Participant Information Sheet: Sub Studies, version 1.5, 19 March 2013
5. Participant Informant Information sheet, version 1.2, 19 March 2013
6. GP letter – 1 year post enrolment version 1.0, 15 April 2013

Yours sincerely

Professor Philip Bath