

Mr Robert Johnson  
Vice Chairman  
Nottingham Research Ethics Committee 1  
1 Standard Court  
Park Row  
Nottingham NG1 6GN

April 26th, 2011

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 12<sup>th</sup> November 2009 and we commenced recruitment in September 2010.

I am writing regarding a substantial amendment to the PODCAST trial protocol. The updated version 1.4 of the protocol consists primarily of the following changes in the running of the trial:

1. All patients will have fasting urea and electrolytes, fasting glucose and fasting lipids prior to baseline and follow-up clinic visits.
2. A copy of the ECG from the index event will be collected and an ECG will be performed at each follow-up clinic appointment.
3. The ambulatory blood pressure monitoring, as part of the sub-study, will now be performed at all scheduled follow-up clinic appointments.

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.
2. Protocol Version 1.4 dated 26 April 2011 (with tracked changes and updated document)
3. Participant Information Sheet: Main Study, version 1.4, 26 April 2011
4. Participant Information Sheet: Sub Studies, version 1.4, 26 April 2011
5. Participant Consent Form: Sub Studies, version 1.4, 26 April 2011
6. Participant Consent Form: Screening, version 1.4, 26 April 2011
7. Participant Consent Form: Main, version 1.4, 26 April 2011
8. GP Practice Briefing Letter, version 1.4, 26 April 2011
9. GP Letter: Enrolment, version 1.4, 26 April 2011
10. GP Letter: Patient develops dementia, version 1.4, 26 April 2011

Yours sincerely



Professor Philip Bath